

June 18, 1987

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Room 500 U.S. Customhouse
721 19th Street
Denver, Colorado 80202
303-837-4915

Mr. Howard Roy Curtin, President
Consolidated Research and Technologies, Inc.
d/b/a Esion Corporation
599 West Center Street
Pleasant Grove, Utah 84062

NOTICE OF ADVERSE FINDINGS LETTER

Dear Mr. Curtin:

During an inspection of your firm between December 15 and 18, 1986, serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) were discovered by our investigator. The noted inspection was conducted for the purpose of determining the adequacy of your corrective action on the adulteration and misbranding violations listed in a letter of October 31, 1985 we sent you. The violations were associated with your manufacture and distribution of medical devices (Accupath 1000 and Vi-Tel 618).

Our findings during December 1986 show that you discontinued sale of the Accupath 1000; are still distributing the Vi-Tel 618; and are currently distributing another product called the INTERRO. The INTERRO is a medical device, as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Based on the available information, we do not consider the INTERRO to be a Class II device under 21 CFR 882.1540 (copy enclosed) because it is not used in accordance with that citation. We are aware of situations where your devices are being used in a manner similar to, or the same as the Accupath 1000. Your corrective action to the violations listed in our previous letter are questionable in their reliability since the INTERRO appears to be only a substitute for the Accupath 1000. In addition, there is no documentation that pursuant to 21 CFR 812.2(c)(3) your devices are exempt from the regulation governing Investigational Device Exemptions (IDE's). We note that 21 CFR Part 809 is reserved for in vitro diagnostic products, which your device is not. Therefore, the investigational statement your devices exhibit is incorrect. We recommend you revise the language to that under 21 CFR 812.5.

We have information indicating that diagnosis and treatment of disease conditions are associated with use of your devices. Enclosed is a copy of an article from the January 1987 issue of Nutritional Forum describing use of the INTERRO device at one clinic. Such uses may present risks to subjects undergoing treatment or diagnostic procedures. While we understand from labeling that you do not distribute the device under medical use claims, you also distribute promotional material describing the INTERRO as being better than the Accupath 1000 (copy enclosed). Such actions are, in our opinion,

inconsistent and demonstrate that you are commercially distributing the devices for uses which fall within the definition of a medical device.

We request that you submit documentation to the Federal Food and Drug Administration which demonstrates that pursuant to 21 CFR 812.2(c)(3) the devices are exempt from the IDE regulation. Specifically, you should submit the information:

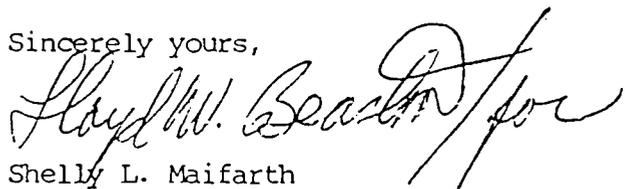
That your device:

- is only diagnostic in nature;
- is noninvasive;
- does not require an invasive sampling procedure;
- does not by design or intention introduce energy into a subject; and
- is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure.

In addition, there should be evidence that an Institutional Review Board (IRB) has been presented a protocol for evaluation and has approved an investigation with your device.

Please advise this office in writing, within thirty (30) days of receipt of this letter, of the steps you have taken or plan to take to address these matters. If the matters outlined in this letter are not addressed with satisfactory corrective actions or explanation, the violations listed in our October 31, 1985 letter may be applicable to your current activities. Your reply should be addressed to Lloyd W. Beaston, Compliance Officer.

Sincerely yours,


Shelly L. Maifarth
Acting, Director of Compliance

Enclosures

1. Copy of Federal Register, Vol. 45,
No. 13, Friday, January 18, 1980 - Medical Devices;
Procedures for Investigational Device Exemption
2. 21 CFR 882.1540
3. Article from January 1987 Nutritional Forum
titled "MY VISIT TO THE NEVADA CLINIC"
4. Promotional flyer for the INTERRO

MELVIN VAL MILLER
ATTORNEY AT LAW*
GOVERNMENT RELATIONS CONSULTANT

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7-218

July 16, 1987

Mr. Lloyd W. Beaston
Compliance Officer
U.S. Food and Drug Administration
Denver District Office
P.O. Box 20087
Denver, Colorado 80225-0087

Re: Notice of Adverse Findings Letter, June 18, 1987
Esion Corporation (Registration No. 1720813)

Dear Mr. Beaston:

It was a pleasure talking with you on the phone yesterday. Per that conversation, I am including an outline of the actions Esion Corporation has taken, and will take, to address questions raised by the Food and Drug Administration (FDA) in a Notice of Adverse Findings Letter dated June 18, 1987.

As I am sure you are well aware, large and small companies alike find FDA regulations extremely complex. FDA has recognized that the vast majority of companies involved with the research and manufacture of medical devices are small and economically quite fragile. As a result, the FDA established the Small Manufacturers Assistance office as part of the Center for Devices and Radiological Health (CDRH). There are a number of companies which intentionally disregard or try to circumvent the FDA regulations to the detriment of an uninformed public, but I can assure you that Esion Corporation does not fit into that scenario. They, like many small companies, find the regulations extremely difficult to understand, but have continuously attempted to act in good faith. They have committed a significant amount of resources (financial and personnel) in an attempt to maintain continuous compliance with the regulations.

I would like to share with you an event that occurred some time ago which I believe is evidence of Esion Corporation's "good faith" effort to comply with FDA regulations. Dr. Curtin traveled to Washington, D.C. and sought legal counsel regarding his proposed project. Dr. Curtin was advised that the IDE exemption contained in 21 CFR 812.2(c)(3) applied to his situation, and that since the INTERRO does not present a risk to a participant, IRB review was not necessary.

I find Dr. Curtin to be an extremely intelligent man. He had reviewed the regulations and reached what he believed to be an accurate opinion, but still sought legal advice which confirmed his opinion to be correct. Esion Corporation relied on that advice until retaining me earlier this year.

Mr. Lloyd W. Beaston
NAF Response -- Esion Corp.
July 16, 1987
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I am not in the habit of second guessing another attorney's advice, so I advised Esion Corporation, that even though IRB review may (arguably) not be required, the safest approach (to avoid FDA regulatory action) would be to obtain IRB review. Dr. Curtin was in full support of taking the more conservative approach and agreed in early April 1987, to start gathering the necessary information to present to an IRB. Certainly, the NAF letter has influenced our time schedule, but I can assure you that Dr. Curtin had decided well in advance of receiving the NAF letter to seek IRB review. My first draft of documents described below was mailed on May 14, 1987.

I have worked closely with Dr. Curtin in reviewing the appropriate regulatory approach for their project. On behalf of Esion Corporation, I met with Glen Norton, Small Manufacturers Assistance, CDRH, on several occasions in May to discuss the IDE exemption under 21 CFR 812.2(c)(3) and a "best approach" for a future premarket notification submission. At the recommendation of Mr. Norton, I prepared numerous FOI requests for 510 k submissions in order to determine, to which if any, we may be found to be substantially equivalent.

In the mean time, Dr. Curtin and I have prepared final drafts of an informed consent form (21 CFR Part 50), documents for investigators which sets forth their regulatory duties (which includes a signed statement that they will not use the INTERRO without confirmation by another medically established diagnostic product or procedure), other miscellaneous documents for presentation to an IRB (21 CFR Part 56), and are currently preparing a draft protocol. We are attempting to have all the necessary information assembled to present to our IRB for review in August.

As we discussed yesterday, I will provide a more detailed response and ask that the IRB send you copies of their findings by August 31, 1987.

Thank you for your consideration in this matter. If you have any questions, please feel free to contact me at (202) 546-0601.

Sincerely,



M. Val Miller

MELVIN VAL MILLER
ATTORNEY AT LAW*
GOVERNMENT RELATIONS CONSULTANT

October 16, 1987

(By Express Mail)

Mr. Lloyd W. Beaston
Compliance Officer
U.S. Food and Drug Administration
Denver District Office
P.O. Box 25087
Denver, Colorado 80225-0087

Re: Supplemental Response to Notice of Adverse Findings
Letter, June 18, 1987, Esion Corporation (Registration
No. 1720813)

Dear Mr. Beaston:

I have wanted to prepare this supplemental response to my earlier letter dated July 16, 1987 for several weeks, but hoped to have received written confirmation from the Institutional Review Board (IRB) to include for your review.

We anticipated making a presentation to the IRB the third week in August, but due to conflicts in schedules of myself and the IRB we were unable to make a presentation until September 26, 1987. Please find below a description of the IRB members, the materials reviewed and the findings of the Board.

IRB MEMBERS:

Robert Detweiler (Chairman);
Dr. Darrell Weber, Ph.D. (Non-physician Scientist);
Dr. Dennis Heaston, M.D. (Physician);
Carol Harmer;
Gail Metcalf; and
Gail Brown, IRB Secretary (Non-voting position).

I have reviewed in detail the IRB requirements in 21 CFR Part 56 and consider this board to be in complete compliance with the regulations. Dr. Curtin, President of Esion Corp. expressed some concern about Gail Brown serving as the secretary of the IRB because she is an employee of Esion. I assured Dr. Curtin that this didn't present even the slightest problem, in that, most IRB's I have dealt with are composed largely of employees of the institution or clinic actually conducting the investigation. None of the voting members of the Board are employed by Esion, and Ms. Brown serves a strictly administrative function.

Mr. Lloyd W. Beaston
Supplemental Response -- Esion Corp.
October 16, 1987
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Dr. Heaston has a strong background in clinical investigations and provided a great deal of expertise to the group. Dr. Weber is a faculty member of Brigham Young University and also adds a great deal of experience to the Board in the non-medical scientific field. The other three members are respected citizens of the business and religious community.

MATERIALS REVIEWED:

I provided verbatim copies and reviewed in detail with the IRB the following regulations:

1. 21 CFR 812 et seq., Medical Devices; Procedures for Investigational Device Exemptions (IDE) as published January 18, 1987 in the Federal Register (45 Fed. Reg. 3732); and
2. Informed Consent requirements as codified in 21 CFR Part 50.

During the meeting a great deal of time was devoted to those portions of the preamble in the above-mentioned notice which dealt with protection of the rights and safety of subjects, informed consent requirements, significant vs. nonsignificant risk devices, and reporting requirements of adverse device experiences.

Dr. Curtin explained the Interro and Vi-tel and investigational plan in detail and then demonstrated the devices to each member of the group. A question and answer format was used during every portion of the meeting.

A sample Informed Consent form was presented to the IRB for approval in its present form or with any revisions the Board considered appropriate.

FINDINGS OF THE IRB:

I had wanted to include a copy of the IRB letter to Esion Corporation, but decided against delaying this response further. I will forward a copy of their letter as soon as it is received.

The Board found that the Interro and Vi-Tel do not pose any significant risk, and therefore, concluded that they are nonsignificant risk devices. Additionally, the IRB reviewed the investigational plan and sample informed consent form and approved each. The IRB did not request that we be reviewed more

Mr. Lloyd W. Beaston
Supplemental Response -- Esion Corp.
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Page 3

often than annually, but Esion offered to provide periodic reports during the course of the investigation.

CONCLUSION:

Esion wants to be responsive to any concerns that you have, and will provide any additional information you need. They anticipate conducting a study in conjunction with a teaching university in Texas, and will be seeking IRB review in that and other areas of the country. We will be happy to provide copies of all correspondence received from each IRB if you desire.

If you have any other questions, please feel free to contact me at the address above.

Sincerely,



M. Val Miller

CONSOLIDATED RESEARCH & TECHNOLOGIES, INC.
DBA ESION CORPORATION
599 West Center Street
Pleasant Grove, Utah 84062
5/7/86 DTL

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SUMMARY OF FINDINGS

This inspection was a workplan inspection to follow up on a NAF letter sent to the firm on October 31, 1985. The initial FDA inspection of this firm found them to be manufacturing two galvanic skin response (GSR) testing devices which were used in the diagnosis and treatment of diseases. The firm had no GMP compliance, had not registered, and had not made premarket notification submissions for either device.

Since the initial inspection, this firm has discontinued one of its devices and has replaced that device with a similar computerized diagnostic device. However, the firm has changed its labeling to take advantage of investigational device exemption provisions under 21 CFR 812.1(a). The firm also is taking advantage of exemptions from IDE regulations as provided in 21 CFR 812.2(c)(3). The firm claimed to have discussed these new labeling and marketing procedures with an attorney.

No FD483 was issued to management at the close of the inspection. Although GMP procedures did not appear to be followed during inspection, the firm's devices appear to fall under the exemptions from IDE regulations.

HISTORY OF BUSINESS

Information in this section has not changed significantly since last inspection. The firm now does business as ESION Corp. although it is officially Consolidated Research and Technologies, Inc. Officers of the firm remain the same.

As previously reported, the firm has discontinued manufacturing one of its medical devices. That device is the Accupath 1000 which was the primary device which the firm was manufacturing during the initial inspection.

This inspection revealed that the firm has discontinued manufacture of the Accupath 1000, but has replaced it with a functionally similar device called the Interro. The Accupath 1000 was a 6502 based microcomputer with a GSR analog probe coupled to an analog/digital modem device and operated by proprietary software. The new device, the Interro, is sold as a series of peripheral devices for operation with computer or compatible computers (8088 CPU controlled). Refer to Ex. 1 which is a brochure describing the Interro device. The firm sells sample trays, an Interro matrix unit, a transducer module, and a computer expansion board, along with software to control these peripherals.

1000

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DBA ESION CORPORATION
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Dr. Curtin said that there is a planned expansion of the firm to employees. The firm has acquired adjoining offices and is approximately times larger than it was when I first inspected it. The new facilities provide space for quarantine, accounting, shipping control, research, incoming goods receiving, assembly, and inspection.

PERSONS INTERVIEWED AND ADMINISTRATIVE RESPONSIBILITY

Credentials were shown and an FD482 issued to Dr. Howard Roy Curtin, President. Dr. Curtin accompanied me throughout the inspection, supplied information, and participated in the discussion with management. He acknowledged that he is the most responsible individual in the firm's operations and reported that officers of the firm remain unchanged from those of the previous inspection. Dr. Curtin also said that there had been no significant management changes since the previous inspection.

OPERATIONS

As previously reported, the firm manufactures two galvanic skin response tester devices. The Vi-Tel 618 was discussed during the previous inspection. It is a simple galvanic skin response tester. The Accupath 1000, formerly made by this company is no longer being manufactured and Dr. Curtin said that existing units have been systematically removed from field service. He said that , the marketing firm which had ordered the products from Consolidated Research and Technologies, was now out of business and had left Consolidated Research and Technologies holding a debt.

The firm's new device, the Interro, is described in the brochure attached to the report as Ex. 1. The disclaimer/labeling attached to the report as Ex. 2

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is applicable to both the Vi-Tel 618 and the Interro. The firm maintains that these devices are diagnostic devices used as investigational devices. Labeling has been reworded to give the devices investigational intent. The exemptions referred to in Ex. 2 summarize the situation. Both the Vi-Tel 618 and the Interro are being promoted as investigational devices under 812.1(a) of the device regulations, the firm's devices (if given investigational device exemption) are exempted from misbranding, registration, listing, premarket notification, report keeping, GMP compliance, and other requirements of the device regulations. The firm also claims to be exempt from IDE requirements because of 812.2(c)(3). See Ex. 2 and the referenced regulation. The firm claims the Interro and the Vi-Tel 618 are non-invasive, do not require invasive sampling procedures that present significant risk, do not introduce energy into a subject, and are not used as the sole source of diagnosis. The firm also claims to comply with Section 809.10(c) which is specified in regulations section 812.2(c)(3). Again, refer to Ex. 2 which details the firm's disclaimer and labeling relating to use of their devices for diagnostic purposes under IDE exemption.

Labeling attached to the report as Ex. 3 was observed attached to Interro matrix units held in the firm's finished goods quarantine area. I saw Interro units stored there. The firm also had Vitel 618's in this same room, but none of those bore the labeling attached as Ex. 3. Mr. Curtin said the labeling would be attached before the products were shipped. He said the firm has not promoted the Vi-Tel 618 since my prior FDA inspection. The label attached as Ex. 3 was designed to comply with Section 809.10(c)(2)(ii). Dr. Curtin said he had just met with the firm's attorney and claimed that the statements included in Ex. 2 were approved by their attorney and should comply with FDA regulations. Note that p. 2 of Ex. 2 references Section 809.10(c)(2)(iii) which was not present in my 1984 version of the 21 CFR regulations. Dr. Curtin apparently took this section from the 1983 version of the device regulations. Dr. Curtin said in reference to that that his firm owes us a letter that they were distributing their exempt investigational devices under that section of the regulations. He said that section of the regulations does not say when he owes us the letter. He did say that he intended to notify us.

During inspection, the firm was assembling Interro matrix units in its assembly area. Since Dr. Curtin claimed that these devices are exempt from IDE requirements, the manufacture of those devices was not examined in detail. I did examine the facilities to see whether any Accupath 1000 devices were present and none were found. I also examined the premises for suitability for device manufacturing. Since the firm had just moved into expanded facilities, the room designations were not in complete use. The firm does have adequate space for location of quarantine, finished device inspection, incoming goods receiving, assembly, and other operations.

7-11-86

Dr. Curtin and I discussed the theory of hololinguistics. He supplied me with a book titled The Grammatical Man written by Jeremy Campbell, which he asked me to include as an exhibit to the report. Copies of the book cover and table of contents for the book as well as the beginning pages to one chapter of the book are attached as Ex. 4 to this report. This investigator found little correlation between theories written in the book and the theories described by Dr. Curtin. Dr. Curtin discussed the traditional allergy treatment approach. He said the allergist puts more of the allergy-producing substance into the person's body until the body gets desensitized. He claimed there was a second approach in which studies would be made to identify any associations with decisions which a person's body might make. He described neutralizing dose therapy in which dilutions of allergy-causing substances would be tested on a person's body until the exact dilution ratio was found. He claimed that that ratio would cause reactions to cease because the exact dilution ratio would provide the body with proper information and let it re-decide how to react to the allergen. Dr. Curtin went into a discussion of right brain and left brain functions. He described hololinguistics as a field of study in which autonomic or subliminal responses in the body are sensed, thereby bypassing the mind's disguising of body responses. He gave an example where an allergist might ask a person whether the person was sensitive to corn. The person might reply he was not allergic to corn, while his body might give a different answer which could be sensed using a device such as the Interro. He claimed that this field of study was being investigated and the Interro device was merely an investigational tool to allow such study to continue. He said the skin conduction response module (GSR) was the only one available for the Interro. He discussed other possibilities such as sensors which would measure brain waves, muscle response, and magnetic responses around the body. I noticed that the outer door to Dr. Curtin's secretary's office and his inner office bore a nameplate saying "CONSULTATION". The brochure attached as Ex. 1 to this report also describes the ESION hololinguistic seminar which teaches the operation of the Interro system.

OBJECTIONABLE CONDITIONS OR PRACTICES

Because of the exemptions claimed by the firm, the firm may be exempt from registration and GMP compliance. The firm has not registered during the current year. Dr. Curtin said they would register when they started to manufacture the

DISCUSSION WITH MANAGEMENT

Dr. Curtin and I discussed the NAF letters which issued to the firm earlier. He claimed the Accupath 1000 was a problem of which is now out of business. The labeling for that device was reportedly developed by We discussed the NAF letter reference to Section 502(F)(I) during our discussion. Dr. Curtin said it does not apply since both the device labeling and the device usage have changed for the Vi-Tel 618 and

DUPLICATE

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since the Accupath 1000 is no longer distributed.

Dr. Curtin claimed he owed FDA a notification of shipment per device regulation 809.10(c)(2)(iii). He was quite knowledgeable about FDA regulations and said he had discussed those with an attorney who was confident the firm's position was legally sound. I told Dr. Curtin I could not make an evaluation of the firm's position, but that I would report details of the firm's operations as well as its position on claiming exemption for its medical devices. Dr. Curtin agreed that the firm would have to comply with device GMP regulations and other regulations when it began manufacturing its _____ and Dr. Curtin stated that he fully intended to do so. He said the firm would register, submit 510(k) notification to us, and would be in compliance with all applicable device regulations when it begins manufacture of the _____

EXHIBITS

During the inspection Dr. Curtin provided me with Ex. 1-4 which are summarized below. Ex. 1 is a brochure for the Interro device. Ex. 2 is a disclaimer letter which is included with the report as labeling. The firm also included a statement of purchaser which is p. 3 of Ex. 2. This statement of purchaser describes whether or not the product (Interro or Vi-Tel) will be used in medical diagnostic procedures. Note that the firm is claiming its devices are not significant risk devices and therefore are not subject to IRB review. Ex. 3 is a copy of the firm's investigational device labeling used by them to comply with Section 809.10(c)(2). Ex. 4 is selected pages copied from a book titled "The Grammatical Man" written by Jeremy Campbell. The entire book was submitted by Dr. Curtin as an exhibit. This investigator will maintain the entire book for the near future, but only selected pages were taken from it for inclusion in the report, since the index does not include reference to hololinguistic theory, which is the basis for the Interro and Vi-Tel 618 devices.


DARRELL T. LEE

Investigator
Salt Lake City Resident Post

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DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER Bldg #20 Denver Federal Center Denver, Colorado 90225 (303) 236-3000	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: <i>Vaughn Cook</i>		DATE OF INSPECTION 4/20, 25/88	C. F. NUMBER
TITLE OF INDIVIDUAL <i>Vaughn Cook, Dir. Performance</i>		TYPE ESTABLISHMENT INSPECTED Medical device establishment	
FIRM NAME DBA ESION CORP. Consolidated Research & Technologies, Inc.		NAME OF FIRM, BRANCH OR UNIT INSPECTED Manufacturing plant	
STREET ADDRESS 599 West Center		STREET ADDRESS OF PREMISES INSPECTED same	
CITY AND STATE Pleasant Grove, Utah		CITY AND STATE same	
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
1. The firm has failed to prepare and implement a quality assurance program for the manufacturing process of the Interro or the Vitel. For example: <ul style="list-style-type: none"> a) There is no auditor designated. b) There is no record of any audit ever performed. 			
2. The firm has deficient manufacturing specifications and processing procedures to assure that the device(s) conform to its original design or any approved changes in that design; for example: <ul style="list-style-type: none"> a) There is no formalized document approval system for documents used in initial manufacturing steps. b) There is/are no records of Quality Control procedures performed for in-process manufacturing steps. c) There are no documents identifying the responsibilities of individuals performing critical manufacturing steps. d) There is no procedure for finished device testing stating how to perform, what test devices are used, and who will perform such testing. e) The device master record does not contain copies of all labeling currently in use. f) There are no written calibration procedures for equipment used in manufacturing, there are no records of past calibrations on these instruments. g) There are no reprocessing ^{procedures} to assure that the device or component meets the original or subsequently modified and approved specifications. h) There are no procedures for packaging to assure the device is not damaged during shipment and to assure all components and instructional material are packaged properly. 			
3. The firm has failed to implement and maintain a complaint handling system relative to the identity, quality, durability, reliability, safety, effectiveness or performance of the Interro or Vitel. There are no designated individuals to handle complaints.			
4. There are no documented training programs for employees performing critical manufacturing steps.			
5. There is/are no records of validation on the software used in the Interro to support a high degree of confidence that the system will consistently do what it is supposed to do.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE <i>Luis C. Chavarria</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Luis C. Chavarria CSO

SUMMARY OF FINDINGS

This inspection of a medium-size GSR medical device was conducted per CP 7382.830C. The inspection also covered information on the actions that have resulted from a Notice of Adverse Findings letter that was issued to the President of the firm, Dr. Howard Roy Curtin on 6/18/87.

The inspection included the issuance of two Notice of Inspections on 4/20/88 and 6/22/88. The second Notice was issued to Dr. Howard Roy Curtin to obtain additional information on the use of the Interro and the Vitel 623. Contact with Dr. Curtin was not possible at an earlier date due to Dr. Curtin's travel schedule.

The Notice of Adverse Findings letter issued on 6/18/87 requested Dr. Curtin submit information on the Interro and Vitel being: only diagnostic in nature, non-invasive, not requiring an invasive sampling procedure, not by design or by intention introducing energy into a subject, and not being used as a diagnostic procedure without confirmation of the diagnosis by another.

In addition, the NAF letter requested confirmation that Dr. Curtin has presented a study protocol for evaluation to an Institutional Review board.

This inspection revealed the firm has not filed a 510(k) or complied with the NAF letter request. Statements made by Dr. Curtin and other employees of the company to the investigator revealed the firm continues to operate without any changes that have been requested by the FDA in its NAF letter to Dr. Curtin.

Dr. Curtin also provided specific documentation, such as a copy of a "Consent Form" distributed by him to his clients that use the Vitel and Interro in Medical Research.

Dr. Curtin allowed the investigator to view some correspondence between him and a _____ stating the Interro had been used in a "study" involving AIDS patients. The specific date observed in this letter is included in the section titled _____

Additional literature was collected which is used as promotional material for the Interro and the Vitel. This included a VHS videotape provided by Dr. Curtin. The literature that was collected includes claims that associated Interro and Vitel with medical claims. It should be noted that certain records were provided by top management during the first part of the inspection, and other records were provided by Dr. Curtin, who refused selected data which is explained in this report.

An FD483, Inspectional Observations, was issued to Mr. Vaughn Cook citing: failure to conduct internal audits, failure to have complete Device Master Records, failure to maintain a complaint file and procedure for handling complaints, and failure to validate the software used in the Interro.

Documentary sample DOC-88-486-301 was collected to show interstate distribution of the Interro.

PIKED

CONSOLIDATED RESEARCH & TECHNOLOGIES
DBA ESION CORPORATION
170 S. Main Street
Pleasant Grove, UT 84062
EIR: 4/20,25 & 6/22/88 LCC

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HISTORY OF BUSINESS/CORPORATE OFFICERS

The firm has ^Moved its headquarters since the previous inspection 6/18/87 from 599 West Center Street, Pleasant Grove, UT to a new building at 170 South Main Street, Pleasant Grove, UT. The manufacturing plant has also moved from 599 West Center to 280 South Main Street, Pleasant Grove.

The corporate officers, Dr. Howard Roy Curtin, President, and Patricia Curtin, Corporate Secretary, maintain offices at the 599 West Center Street address. All post-inspectional correspondence should be sent to:

Dr. Howard Roy Curtin (Ph.D. Physics)
170 S. Main Street
Pleasant Grove, UT 84062
1-800-367-7550

District files contain a copy of Notice of Adverse Findings dated June 18, 1987 and a response from Dr. Curtin's attorney, Melvin Val Miller, 300 I Street, N.E., Suite 204, Washington, DC 20002.

Dr. Curtin stated he was in the process of gathering data for a 510(k) submission, since his devices are currently being used with some medical applications. This statement was made to the FDA investigator during the inspection of December 15 and 17, 1986, at which time Dr. Curtin claimed exemption from IDE regulations and refused to allow a GMP inspection.

Dr. Curtin also made the statements in reference to gathering 510(k) data during the inspection of 5/7/86 on the Vital 618, a similar device to the current version, Vi-Tel 623.

The above stated history was reiterated to Dr. Curtin, who admitted knowledge to the multiple NAF letters. He said the device is not a medical device, it is a harmless "pre-diagnostic" device designed to communicate information to, and receive responses from, that part of the mind that controls body functions. It translates this information into the language of numbers and words understood by the conscious mind.

INDIVIDUALS INTERVIEWED/INDIVIDUAL RESPONSIBILITY

On 4/20/88 credentials were shown and Notice of Inspection was issued to Mr. Charles Goodman, Company Controller. Mr. Goodman, by his own admission, was the most responsible individual present during initial contact with the firm. Shortly thereafter we were met by Mr. Vaughn Cook, Director of Professional Services. Messrs. Goodman and Cook share management duties when Dr. Howard Roy Curtin is absent. The interview of Dr. Curtin was not possible until 6/22/88 due to the investigator attending a training course and Dr. Curtin was out of town.

On 6/22/88 credentials were shown and Notice of Inspection was issued to Dr. Howard Roy Curtin. Dr. Curtin, by his own admission, represented himself as the most responsible individual for all affairs. He signs checks and hires

PURGED

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and dismisses employees. He was observed giving orders to all employees during the course of the inspection. No one questioned his orders.

Dr. Curtin also identified himself as the inventor of the Interro and the Vitel 623.

Dr. Curtin was asked what he had done to correct the items listed on the NAF letter dated June 18, 1987. He stated he did not acknowledge the letters because the observations pertain to a Medical Device, and his device is not a medical device.

Mr. Miller in his letter to Denver District Compliance dated July 16, 1987, states Dr. Curtin will attempt to present IRB with all the necessary information for a study protocol.

FIRM'S TRAINING PROGRAM

The firm does not have a formalized written training program. All training is on-the job; there are no records indicating who has received specific training.

COMPONENTS

All printed circuit boards are manufactured by
. The metal cases are made by
. The computer 82088 boards are Compatible
supplied by various vendors ().

NAF LETTER FOLLOW-UP

On June 18, 1987, ESION Corporation was issued a Notice of Adverse Findings letter for lack of a 510(k) or IDE regarding distribution of medical devices (Accupath 1000 and Vitel 618). The letter requested from the firm's President the following information which demonstrates that pursuant to CFR 812.2(c)(3) the devices are exempt from the IDE regulation:

1. Is only diagnostic in nature
2. Is non-invasive
3. Does not require an invasive sampling procedure
4. Does not by design or intention introduce energy into a subject
5. Is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure
6. In addition, there should be evidence that an Institutional Review Board (IRB) has been presented a protocol for evaluation and has approved an investigation with your device.

The information was provided by Dr. Curtin verbally on 6/22/88. He did not present evidence of having written to the FDA in response to the NAF letter issued on 6/18/87.

Dr. Curtin's responses:

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Item 1. Dr. Curtin stated the Interro and Vitel 623 are both very similar Galvanic Skin Response devices. The only difference in the Interro is the P.C. attached to the GSR, which displays the readings in bar graph form on a monitor and can also send the data to a printer. The Vitel will display the readings in a meter only. Both devices are used by "Health Professionals" in a Pre-diagnostic stage. (Dr. Curtin explained "Health Professionals" as medical doctors, chiropractors and therapists.)

Dr. Curtin provided me with an example of how the Vitel or Interro is used. He said in traditional allergenic testing the medical doctor would give the patient several injections of the suspected substance that was causing an allergic reaction to the patient. The expense for the diagnostic procedure would be high since usually several injections were required. Using his devices, the doctor would "test" the patient's stress response to the suspected substance that is causing the allergy and by the Interro's readings he will eliminate the need for most of the different injections containing the different concentrations of the suspected allergy-causing substance. The doctor might still need to use some of the shots of the allergenic substance but will cut down on the number of injections he needs to achieve the result and determine if the patient is allergic to the substance or is not allergic. Dr. Curtin said his devices are pre-diagnostic but do not take the place of traditional medical procedures. Dr. Curtin said the substance he referred to in his explanation could be anything from a "carpet" to a vitamin.

Items 2,3: Dr. Curtin explained how the Interro and Vitel are non-invasive and do not require an invasive sampling procedure. He said the device is basically the same as any other Galvanic Skin Response device, the "patient" holds a probe in one hand and the "practitioner" will touch the patient on the designated points on the other hand. (The points are the same as acupuncture points except for non-invasive probing.) The resistance is measured by a meter on the instrument that contains a reading of 0 to 50 positive and 0 to 50 negative. If the practitioner obtains a positive reading, the instrument is "calibrated" to the center of the meter, which is zero (0).

The second step in the testing procedure once the meter has been set to zero, is placing the substance (possible allergenic) on one of two metal trays on the instrument. The patient is holding the metal rod in one hand, which is connected to the metal plate and the metal plate is connected to the touch probe. The practitioner eventually forms a complete circuit by touching the patient on the designated acupuncture points. The instrument once again registers either positive or negative readings affected by the item that is placed on the trays.

Dr. Curtin said the positive or negative readings are "interpreted" as stress causing or stress draining on the patient. A substance that causes stress to the patient is allergenic to the patient. If the patient is determined to be allergic to a specific substance, the patient is given instructions to avoid contact with the substance.

Item 4. As explained earlier in this report, the "patient" being tested holds one metal rod in one hand and is touched on the other hand by a probe. The

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device operates on four penlite "AA" batteries and must complete an electrical circuit to display a reading on the meter. Dr. Curtin did not have written documentation on any testing to indicate the strength of the current flowing through the probe. Dr. Curtin stated it was minimal, similar to a flashlight.

Item 5. As explained in Items 2 and 3, the instrument as explained by Dr. Curtin is used as a pre-diagnostic instrument, and not solely as a diagnostic.

Item 6. Dr. Curtin did not present any evidence that he has presented a protocol to an IRB for evaluation. He said he had presented an IRB with a protocol but declined to state when and where or the name of the IRB or if he had received approval.

GUARANTEES AND LABELING AGREEMENTS

Dr. Curtin stated there are no labeling agreements. The only guarantee given by his firm pertains to the operational characteristics of the _____ compatible computer that accompanies the Interro.

FIRM'S TRAINING PROGRAM

The firm does not have any type of documentation on the _____ employees. This was cited as Item 3 on the FD483.

OPERATIONS/OBJECTIONABLE CONDITIONS

A brief GMP inspection was made to see if the firm was complying with Medical Device GMP's in any respect.

The firm's manufacturing activities are conducted on demand of the sales department. Dr. Curtin accompanied me to the manufacturing building located at 280 South Main, Pleasant Grove, UT.

The firm does not perform internal audits. None of the personnel had any knowledge on how to perform an audit, and there was no written documentation of an audit ever performed (Item 1 on FD483).

The schematics for the PC boards used in the Interro and Vitel 623 are kept in a binder, but the firm does not have any system that entails signatures and dates of approvals. These observations were cited as Item 2a,b and c.

The firm does not perform routine calibration on equipment used in manufacturing, such as voltage/ampere meters. This was cited as Item 2f on the Notice of Observations.

The firm will also repair some units that are returned from the field. There are no contracts to control component mix-up or procedures for reprocessing units or components that fail. This was cited as Item 2g on the FD483.

COMPLAINTS

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The firm does not maintain a complaint file, nor does it have a formalized complaint handling procedure. There is no designated unit to handle complaints (Item 3 on FD483).

INTERRO COMPUTER SOFTWARE

The Interro (Ex. 1) is also a Galvanic Skin Response unit, with the same basic resistance technology used in the Vitel 618 and 623. The major difference in the Interro is the display hardware. The unit has the same PC boards and operates identical to the Vitel. The "patient" is instructed to hold a rod while the "examiner" touches different points on the patient's other hand. The resistance, or in Dr. Curtin's terms, "stress level" is displayed on a CRT screen after being processed through an IBM Compatible 828088 base computer. The software was developed in-house by a software designer. There has never been any validation study on any of the software. This observation was cited as Item 5 on the FD483.

OTHER USES OF THE INTERRO/VITEL (AIDS)

Dr. Curtin explained that although his devices are "currently" not being used in a "medical sense", he has knowledge that some doctors are currently using the Interro and Vitel for medical studies and have had fantastic results. I asked Dr. Curtin if he had any type of documentation that I could review that showed where and when these studies have been conducted. Dr. Curtin said he had several letters from doctors he would allow me to see momentarily, only he did not want me to have a copy of any documents.

The first letter Dr. Curtin allowed me to glance at was a letter from a [redacted] addressed the letter to Dr. Curtin and in the letter he discussed some cooperation from a [redacted] of the Centers for Disease Control on a "study" he is conducting on the Interro's ability to diagnose AIDS. The letter was written on formal business letterhead containing [redacted] office address. The letter was dated [redacted] and contained the following addresses:

The letter was signed [redacted] Dr. Curtin would not discuss this letter any further. Once Dr. Curtin noticed I was reading the letter carefully, he took it from me and did not allow me to see it again. He said he was concerned the information on the letter will have some "legal" ramifications.

Dr. Curtin also allowed me to glance at a letter from [redacted]. As I was glancing at the letter from [redacted] Dr. Curtin provided me with Ex. 4a, which he said explains a technique "Sublingual Provocative-Neutralization Technique" which is used in conjunction with the Vitel and Interro. In this procedure,

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the practitioner will test the patient in the way as stated previously in this report; the patient is tested against some 64 different solutions. This is possible with the Interro, which has a tray designed to hold up to 25 vials at one time. The computer can switch the connection from one vial to another by pushing a key on the keyboard. Once the practitioner detects the solutions the patient is "allergic" to, the patient is given some of the solution to bring him back to a balance of 50 on the meter. The solutions are purchased independently by the practitioner. Dr. Curtin said his company does not sell the solutions, called Phenolics.

DISTRIBUTION

Dr. Curtin refused all information on interstate shipment documentation for the Interro sold to

NOTE: On 4/20/88 sample #DOC 88-486-301 was collected from Mr. Vaughn Cook. The sample included a Packing List for the Interro. The Packing List contained the item Phenolics (No. 23). Dr. Curtin was adamant his company does not sell the Phenolics; he did not have an explanation as to the reason for having the Item 23 on the Packing List.

INTERTECH TRADING COMPANY

On 4/26/88, after a visit to

, it was learned that he used to be a practitioner using the Vitel in competition with the Phenolic solutions. , who no longer uses the Vitel or Phenolic solutions due to difficulties with the State of Utah regulations, stated he used to buy the Phenolics from a company called

stated he always dealt with the owner of the business, . Consequently, was visited but the employee that was present at the firm would provide no information other than the owner of the business (see memorandum dated).

NOTE: Inspection of all the ESION buildings did not reveal any Phenolic solutions and Dr. Curtin denied having any solutions in his possession. Dr. Curtin stated the solutions are mailed directly from to practitioners wishing to use them. A product catalog was provided by an employee refusing to give her name at . The catalog does not list "Phenolics" as an item sold by the firm.

DISCUSSION WITH MANAGEMENT

Since the inspection was conducted in two parts, a discussion was held on 4/25/88 with Mr. Vaughn Cook at 170 S. Main Street, Pleasant Grove, UT. An FD483, Notice of Observations, was issued for various CGMP violations.

1. The firm has failed to prepare and implement a quality assurance program for the manufacturing process of the Interro or the Vitel. For example:
 - a) There is no auditor designated.
 - b) There is no record of any audit ever performed.

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2. The firm has deficient manufacturing specifications and processing procedures to assure that the device(s) conform to its original design or any approved changes in that design; for example:
 - a) There is no formalized document approval system for documents used in initial manufacturing steps.
 - b) There is/are no records of Quality Control procedures performed for in-process manufacturing steps.
 - c) There are no documents identifying the responsibilities of individuals performing critical manufacturing steps.
 - d) There is no procedure for finished device testing stating how to perform, what test devices are used, and who will perform such testing.
 - e) The device master record does not contain copies of all labeling currently in use.
 - f) There are no written calibration procedures for equipment used in manufacturing, there are no records of past calibrations on these instruments.
 - g) There are no reprocessing procedures to assure that the device or component meets the original or subsequently modified and approved specifications.
 - h) There are no procedures for packaging to assure the device is not damaged during shipment and to assure all components and instructional material are packaged properly.
3. The firm has failed to implement and maintain a complaint handling system relative to the identity, quality, durability, reliability, safety, effectiveness or performance of the Interro or Vitel. There are no designated individuals to handle complaints.
4. There are no documented training programs for employees performing critical manufacturing steps.
5. There is/are no records of validation on the software used in the Interro to support a high degree of confidence that the system will consistently do what it is supposed to do.

Mr. Cook's responses:

- 1a) An auditor will be designated.
- b) Records of all audits will be kept.
- 2a) There will be a formalized document approval system.
 - b) Records of all Quality Control steps performed will be kept.
 - c) All personnel conducting all manufacturing steps will be identified.
 - d) Finished Device testing will be formalized.
 - e) All labeling currently in use will
 - f) Calibration procedures will be written.
 - g) Reprocessing procedures will be written/formalized.
 - h) Packaging procedures will be written/formalized.
- 3) A complaint file will be installed and individuals will be assigned to handle and evaluate complaints.

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- 4) Training programs will be documented and implemented.
- 5) Mr. Cook said he was going to relate the information to the software designers and Dr. Curtin. He could not respond to this item without consulting with them.

On 6/22/88 a discussion was held with Dr. Curtin. All the FD483 observations were once again read to him. He stated the answers provided by Mr. Cook are the official intentions of his company. All the deviations are currently being rectified. He presented me with Ex. 8^a, which he said are the procedures addressed on the FD483 in draft form.

Dr. Curtis stated he was in the process of filing a 510(k) for the Interro and Vitel since they are currently being studied by several doctors. I informed Dr. Curtis about the IDE requirements and the need for a protocol presentation to an IRB. Dr. Curtis said he had a lawyer, Val Miller, 300 I Street N.E., Suite 20, Washington, DC 20002, who was going to file the 510(k) on his behalf.

SAMPLE #DOC88-486-301

This sample, consisting of an Airbill for an Interro from _____ and a "Shipping Checklist" was the only IS documentation either Dr. Curtin or Mr. Cook would provide. All shipments were refused and all information on device inventory was also refused.

REFUSALS

Some data that was refused by Dr. Curtin had been provided by Mr. Vaughn Cook on 4/25/88. Dr. Curtin would not comment on the information that had been given by Mr. Cook. Information and documentation on IS shipment was refused. Data on exact number of devices in the field was also refused. Information on the AIDS "study" conducted by _____ was also refused.

LABELING

Dr. Curtin only provided labeling for the Interro, which consists of two foil labels included in this report in Ex. 9. The first label reads "For Investigational Use Only The performance characteristics of this product have not been established." The second label located on the back panel of the device states "Esion Corp. Pleasant Grove, Utah Model *** S/N ***".

EXHIBITS

The exhibits contained in this report were provided by either Dr. Howard Roy Curtin, President, or Mr. Vaughn Cook, Director of Professional Services. Each exhibit number has the individual who provided the documentation next to the exhibit number. All documentation collected is distributed with the Interro and Vitel.

1. (Curtin/Cook) Interro promotional leaflet

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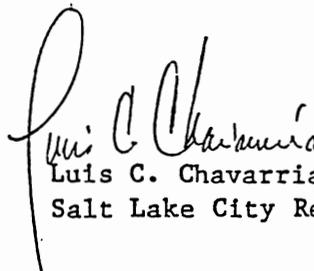
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2. (Curtin/Cook) promotional leaflet Vitel
3. (Curtin) Informed Consent form. Dr. Curtin stated he had his lawyer, Miller, write a Consent Form which was distributed to all Interro users "wishing" to participate in the study.
4. (Curtin) Magazine article from magazine titled The Human Ecologist Vol. 37 Spring 1987. Dr. Curtin had several copies in his office; he said his firm is not associated in any way with the magazine.
- 4a. Article "Sublingual Provocative - Neutralization" Technique
5. (Curtin) Article titled "Using The Interro System in a Medical Procedure". The article is also part of the Interro Training Seminar Manual.
6. (Curtin) 1988 Schedule For Continuing Education and Seminars. Dr. Curtin stated he teaches the courses held at 170 S. Main Street, Pleasant Grove, UT.
7. (Curtin) Interro Training Seminar Two-day Curriculum
8. (Curtin) Invoice No. dtd . Dr. Curtin was asked for an invoice, bill of lading and shipping order. He refused to provide the bill of lading. He only provided a copy of Invoice
- 8a. Device Master Record procedures (draft form)
9. (Curtin) Operator's Guide Vitel 623. NOTE: Section titled "Notes on Testing Protocol". This section mentions the device used as an allergenic agent tester.
10. (Curtin) The Interro System Workbook
11. (Cook) The Interro Training Seminar Manual
12. (Curtin) Interro System Operation Manual. NOTE: Section 8, pp. 14,15 and 16, which explain what is contained in the software of the Interro; the Phenolics are mentioned in sections O,P of Environmental. Page 15 will list symptoms A through Z; the symptoms include Diabetes, Gout, etc. Also take special notice of Table B in Section 8, page 16, the paragraph "Concentration List" for Homeopathic solutions. Dr. Curtin would not elaborate the use of this section (the front of the manual also contains the labels used on the Interro).
13. (Curtin) VHS tape "STS ESION COMPANY, INTRODUCTION TO THE VI-TEL", tape of Mr. Vaughn Cook explaining the use of the Vitel. Mr. Cook mentions the use of the Vitel in "Medical Applications".

Dr. Curtin signed an affidavit stating he provided the investigator with the above stated exhibits.

ATTACHMENTS

1. FD482 (4/20/88)
2. FD482 (6/22/88)
3. FD483
4. Affidavit from Dr. H. Roy Curtin
5. MDR Questionnaire


Luis C. Chavarria, Investigator
Salt Lake City Resident Post