

Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

APR - 5 1985

Re: KR50971
Vegatest Models 1,
2 and 3
Dated: March 2, 1985
Received: March 8, 1985
Regulatory Class: IIIPulse Life
Attn: John Fitzgerald, Director
Route 1, Box 82J
St. Maries, Idaho 83861

Dear Mr. Fitzgerald:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, or to any device which has been reclassified into class I (General Controls) or class II (Performance Standards). This decision is based on the fact that your device uses resistance measurements to diagnose and treat various diseases, and there was no similar device on the market prior to the device amendments.

Therefore, your device is classified by statute in class III (Premarket Approval) under Section 513(f) of the Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires class III devices to have an approved premarket approval application (PMA) before they can be legally marketed, unless the device has been reclassified.

Premarket Approval. To prepare a premarket approval application, statutory provisions appearing in Section 515(c) of the Act must be followed. To assist you in preparing a PMA, we have enclosed a copy of the proposed PMA procedures regulation and a "Guideline for the Arrangement and Content of a PMA."

Investigational Use. In the absence of an approved premarket approval application, a class III device may be distributed only for investigational use. Enclosed is a copy of the investigational device exemption regulation, which must be followed if your device is used in a clinical investigation.

Petition for Reclassification. If you believe that your device should not have to undergo premarket approval before it is commercially distributed, you may petition FDA for reclassification of your device under Section 513(f)(2) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

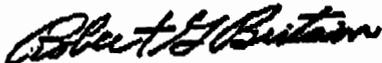
Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFD-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910BEST AVAILABLE
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Any commercial distribution of this device prior to approval of an application for premarket approval or the effective date of any order by the FDA reclassifying your device into class I or II, would be a violation of the Act. Clinical investigations of your device must be in accordance with the investigational device exemption regulation.

If you need any information concerning our decision or the alternatives available to you under the law, please contact Robert F. Munzner, Ph.D., at (301) 427-7226.

Sincerely yours,



Robert G. Britain
Director
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosures

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