DEPARTMENT OF HEALTH & HUMAN SERVICES

APR - 5 1985

Re: KAS0971

Vegetest Models 1, 2 and 3

Dated: March 2, 1985
Received: March 8, 1985
Regulatory Class: II

Pulse Life
Attn: John Fitzgerald, Director
Route 1, Box 620
St. Haries, 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 20, 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)
8767 Georgia Avenue
Silver Spring, Maryland 20993

Best Available Copy
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. Brittain
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures