APR 17 1998

I. 510(K) SUMMARY

Submitted By:

Neal E. Fearnot
President
MED Institute, Incorporated
P.O. Box 2402
West Lafayette, IN 47906
(317) 463-7537
October 3, 1996

Device:

Trade Name:	Swartz Doppler Flow Probe and Monitor System
Common/Usual Name:	Blood Flow Sensor, Flow Probe, Flow Monitor
Proposed Classification Name:	Extravascular blood flow 3probe, 21 CFR Part 870.2120 (74DPT)

Predicate Devices:
The Swartz Doppler Flow Probe is similar to predicate extravascular blood flow probes with respect to intended use, material composition, and method of operation.

Device Description:
The Swartz Doppler Flow Probe and Monitor System is intended for monitoring blood flow in vessels following reconstructive micro-vascular procedures, re-implantation, and free-flap transfers. The Swartz Doppler Flow Probe is supplied sterile and is intended for one-time use. The device is supplied sterile and is intended for one-time use. Reasonable assurance of biocompatibility of the materials comprising the Swartz Doppler Flow Probe is provided by their established history of use in medical product manufacturing.

Substantial Equivalence:
The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Pacemaker Corporation. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 1998

Neal E. Fearnot, Ph.D., E.E.
President
Med Institute, Inc.
P.O. Box 2402
West Layfayette, IN 47906

Re: K964001
Swartz Doppler Flow Probe and Monitor System
Dated: February 18, 1998
Received: February 19, 1998
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX
21 CFR 870.2120/Procode: 74 JOP

Dear Dr. Fearnot:

We have reviewed your section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Swartz Doppler Flow Probe and Monitor System, as described in your premarket notification:

Transducer Model Number

20.0 MHz Swartz Doppler Flow Probe

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g.,

acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact **Rodrigo C. Perez** at (301) 594-1212.

Sincerely yours,

for Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K964001

Device Name: Swartz Doppler Flow Probe and Monitor System

Indications For Use:

The Swartz Doppler Flow Probe and Monitor System is intended for monitoring blood flow in vessels following reconstructive micro-vascular procedures, re-implantation, and free-flap transfers. The Swartz Doppler Flow Probe is supplied sterile and is intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964001

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____