K971010

OCT - 3 1997

510(k) Summary

Safety and effectiveness of NIVP3 are equal or better than for NIVP. The same non-invasive diagnostic instruments are used to provide data inputs to the computer. These are the MD35 Procord (K896034), the TL400 Totalab (K872517), the EC5R Plethysmograph (K932812), and the TD312 Calculating Cuff Inflator K842067). In each case optical isolation is employed to prevent electrical leakage from a computer power supply from reaching the diagnostic instrument, and from there being able to reach a patient. There is no direct electrical connection from the computer to the diagnostic instrument. Data is collected by the computer and incoming waveforms are displayed on the computer screen. The user selects the data to be retained and may edit decision points by moving cursors on the screen. The data is stored in a database using the ACCESS® database engine. A run-time version of ACCESS® is furnished with the program.

No diagnostic decisions are made by the program. The program is not intended to replace the need for a skilled vascular technologist, but is intended to increase the technologist's efficiency by eliminating the need for cutting out chart recordings and writing extensive reports. The advantages of using NIVP3 are that reports are neat and uniform and that patient records are easily stored and retrieved. In some cases tests, like arterial inflow, are semi automated since the program can perform some functions such as inflate a cuff or balance and calibrate the plethysmograph at the correct time to facilitate data collection. Extensive use is made of the Windows® help system to aid the user in operation of the program and give instructions on how to perform certain diagnostic tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 1997

Mr. D. Eugene Hokanson
D.E. Hokanson, Incorporated
12840 Northeast 21st Place
Bellevue, Washington 98005

Re: K970570
Non-Invasive Vascular Program (NIVP3) Version 5.17
Regulatory Class: II (two)
Product Code: 74 DQK
Dated: July 15, 1997
Received: July 17, 1997

Dear Mr. Hokanson:

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 (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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 current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) 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 the 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) 594-4648. 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K970570

INDICATIONS FOR USE STATEMENT

NIVP3 Computer Program (V5.17)

NIVP3 is a computer program which is used with Hokanson vascular diagnostic instruments and an IBM compatible personal computer to produce comprehensive reports. These reports are stored in a computer database and may be sorted, retrieved, and printed. The program allows the user to select and record plethysmographic and Doppler waveforms and blood pressure measurements.. Patient demographics and history are also stored by the program. The user may enter comments to enhance the report.

Arthur A. Ciarkowski

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970570

Prescription Use ✓
(Per 21 CFR 801.109)