

K963578

Premarket Notification [510(k)] Summary

Submitter: JUN 30 1997

I.P.I.- International Products Inc.
8106 Meadow Springs CT
Vienna, VA 22182
phone: (703) 356-6351
fax: (703) 356-5964
e-mail: ipiuwe@erols.com

Contact person: Uwe Klotz
President

Summary was prepared on August 31st, 1996

Name of device: PC-ECG

Classification Name: Electrocardiograph 870.2340

Legally marketed device: CC Cardio-Card (Nasiff Associates)

Distributor: Syracomp, Inc.
phone: (315) 458-0098

Description: Versatile 12-lead electrocardiograph system (ECG) for use with PCs.

Intended use: Recording and display of 1, 3, 6, 12 channels
Monitoring of up to 12 channels with acoustic, analogue and digital pulse signal
Single user system or network ready
~~Comprehensive analysis and measurement functions~~
Storage of unlimited number of 10 sec. ECGs
High quality print of 6, 12 leads with variable speed
Patient database

Technological characteristics:

The two systems compared are very similar in their design. Both units measure the low-voltage signals generated by the heart, amplify the signals, perform an analog/digital conversion and transmit the data to a personal computer (PC) for display and evaluation. The main differences are in the features provided by the software.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Uwe Klotz
International Products Inc.
8106 Meadow Springs Court
Vienna, Virginia 22182

JUN 30 1997

Re: K963578
PC Based Electrocardiograph System (PC-ECG Software Version 4.12)
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: June 4, 1997
Received: June 9, 1997

Dear Mr. Klotz:

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

Enclosure

