K973463

# 510k Summary

- Trade name - Venturi suction electrode patient cable system.
- Common Name - PALJET-B
- Classification name - Electrode Electrocardiograph
- Class II Medical Device---74DRX

FEB 10 1998

The legally marketed device that we are claiming equivalence to is called the WaveTracer this was marketed by Medi-Globe, Inc. We bought the rights to this device along with their existing inventory in 1995. Over time we determined that the configuration of that device the (WT) WaveTracer was not appropriate for the American market so we began a program of re-configuration to satisfy the criteria that was determined appropriate.

We subsequently redesigned the entire electrode assembly using some different materials ( these materials never come in contact with the patient and are made of plastic) these provided for a more reliable electrode. Also a safer electrode because of the elimination of any sharp edges on the contact surfaces that came into contact with human skin. We changed from an AC power source to DC power source reduced the weight and eliminated the hanging arm configuration to enhance the portability aspects of the new device. We made many changes in the mechanical aspects of the machine , however the basic operational aspect of the Paljet is unchanged from the Wavetracer. It is with this fact in mind that we feel that the two systems are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

FEB 10 1998

Mr. Mark J. Hastings
Golden Gate Bio-Devices®
22030 Idena Avenue
Castro Valley, CA 94546

Re: K973663
Trade Name: PALJET-B
Regulatory Class: II
Product Code: 74 DRX
Dated: November 13, 1997
Received: November 20, 1997

Dear Mr. Hastings:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

**510(k) Number (if known):** K973663

**Device Name:** Paljet Patient Cable System

**Indications For Use:** The Paljet-B patient cable system is a reusable ECG suction electrode system. It is designed for diagnostic purposes and is compatible with all electrocardiographs on the U.S. market.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of Cardiovascular, Respiratory, and Neurological Devices**
**510(k) Number** K973663

**Prescription Use** X OR ~~**Over-The-Counter Use**~~
(Per 21 CFR 801.109)