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2. ADMINISTRATIVE INFORMATION

2.1 510(k) Summary

1. Identification of the Device:
   - Proprietary name: **POISE DataEngine**
   - Common Name : Patient Physiological Monitor
   - Classification number: MWI, Class II
   - *Regulation Number: 870.2300*

2. Equivalent legal marketed device:
   - CAPSULE TECHNOLOGIE
   - Datacaptor, **K032142**

3. Indications for Use (intended use) :
   - DataEngine is indicated for use in data collection and clinical information management either directly or through networks with independent bedside devices. DataEngine is not intended for monitoring purposes, nor is the software intended to control any of the clinical devices (independent bedside devices / information systems) it is connected to.

4. Description of the Device:
   - DataEngine is a comprehensive solution to integrate medical device data into HIS. It is also designed to be compatible with XML and HL7. All data collected from medical device is able to transfer to readable format of XML and HL7. Caregiver or nurses will be beneficial from DataEngine, device connectivity software to collect data in real time and receive a complete electronic data for patient's record. Medical staffs do not have to spend much time on manual script. Every patient's real time data will be stored in database server for future research projects, education, and clinical study.

5. Safety and Effectiveness, comparison to predicate devices:

Similarities
   - Same intended use
   - Same output mode
   - Same technological characteristics – software server application, not contact with the patients, not controlling any life sustaining devices

Differences

- Performance differences
  - Can output format other than just text file
  - Support wave form information for some device
  - Support HL7 & Database
  - Can output in Database format, easier to organize
  - Easy to learn

6. Conclusion:

- The new device and the predicate device utilize the similar technologies and design aspects. The subject device is very similar and performs the same clinical function as the predicate device. The main distinguishing characteristics of the subject device are more convenience usage than the predicate device, and they are considered to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2004

Poise Technology Corporation
c/o Ke-Min Jen, Ph.D.
No. 58 , Fu-Chiun Street
Hsin Chu City, 300
Taiwan, ROC

Re: K040969
Trade Name: POISE DataEngine
Regulation Number: 21 CFR 870 2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: MWI
Dated: May 23, 2004
Received: May 26, 2004

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040961

2.2 FDA Indication for Use Form :

Applicant : POISE TECHNOLOGY CORPORATION

510(k) Number : TO BE ASSIGNED

Device Name : POISE DataEngine

Indications for Use :

- DataEngine is indicated for use in data collection and clinical information management either directly or through networks with independent bedside devices. DataEngine is not intended for monitoring purposes, nor is the software intended to control any of the clinical devices (independent bedside devices / information systems) it is connected to.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040961