K032142

AUG - 8 2003

EXHIBIT 2

Capsule Technologie
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Contact: Nicolas Choussat, President

July 10, 2003

510(k) Summary

1. Identification of the Device:
   Proprietary-Trade Name: DataCaptor™
   Classification Name: MWI
   Common/Usual Name: Data Collection Software

2. Equivalent legally marketed device: This product is similar in design and identical in function to the DataCaptor Software, K013019 and K020197. This premarket notification adds compatibility with additional medical devices and upgrades the basic capabilities of DataCaptor.

3. Indications for Use (intended use) The DataCaptor™ System is indicated for use in data collection and clinical information management either directly or through networks with independent bedside devices. DataCaptor™ 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: Based on an open-architecture design, DataCaptor is a data acquisition and distribution software, using ActiveX and the Distributed Component Object Model. This tool retrieves data from serial, network or analog devices and, via an ActiveX control, makes this data available over network or any other type of communication for use in software applications. We do not supply any hardware - our customers can buy cable and connect the devices directly to the COM port (we provide a wiring diagram that shows them pin configurations) or they can use a multiport box or card, an RS-232 to Ethernet converter is used if several devices need to be connected to the network and there are not necessarily computers next to each one. We don't recommend hardware suppliers. The change enables interface to additional models of connected medical devices. Also the DataCaptor Solution now includes the DMM Server module and the DataPortal module. The DMM Server module allows one to process the data originating from the devices and decoded by DataCaptor, i-e, it allows users to create averages, to suppress some data, to streamline the frequency of data that come out of DataCaptor. The DataPortal module converts a dataflow from a Microsoft COM (Component Object Model) container into a TCP/IP Sockets container

5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	DataCaptor Software, K013019 and K020197	Capsule Technologie DataCaptor™ added device support (modification)
Indications for use	Indicated for use in data collection and clinical information management either directly or through networks with independent bedside devices. 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.	SAME
Interfaces	Serial or network	SAME
Where used	Hospitals	SAME
Computer	Windows PC	SAME

6. Conclusion

In all important respects, the "DataCaptor™" Data Acquisition and Distribution Software is substantially equivalent to the DataCaptor Software, K013019 and K020197. The main difference between the two is that modified "DataCaptor™" supports more connected devices and the basic capabilities of DataCaptor have been upgraded..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Kamm and Associates
c/o Mr. Daniel Kamm
Regulatory Engineer
P.O. Box 7007
Deerfield, IL 60015

Re: K032142
Trade Name: DataCaptor™
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm).
Regulatory Class: Class II (two)
Product Code: MWI
Dated: July 11, 2003
Received: July 14, 2003

Dear Mr. Kamm:

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

j) Indications for Use

510(k) Number K032142

Device Name: Capsule Technologie : "DataCaptor™" Data Acquisition and Distribution Software.

Indications for Use: The DataCaptor™ System is indicated for use in data collection and clinical information management either directly or through networks with independent bedside devices. DataCaptor™ 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K032142