K971616

NOV 4 1998

510(k) Summary

General Information

Classification	Class II
Trade Name	DSPM 70
Submitter	Data Sciences International 4211 Lexington Avenue North St. Paul, MN 55126-6164 (651) 481-7800
Contact	Brian Brockway President

Predicate Devices

Mikro-Tip Catheter Pressure Transducer, Millar Instruments, Inc.

Device Description

The DSI Blood Pressure Measurement System (DSPM-70) consists of the following components:

1. Pressure Transmitter with Catheter
2. External Data Receiver
3. Analog Adapter
4. Ambient Pressure Reference
5. External Power Supply
6. Signal Detector
7. Replacement Gel

Pressure Transmitter with Catheter

The pressure transmitter is a small anatomically disc-shaped device that houses the power source (battery), circuitry, RF coil and pressure sensing diaphragm. The transmitter device is

intended to be placed during surgery on the chest and secured with tape. It is a short duration non-permanent product.

A small diameter catheter is integrated with the transmitter and functions as the pressure conduit between the blood stream and the device. This catheter is filled with a fluid and the distal tip is sealed with a biocompatible gel. The gel transmits the pressure of the blood to the internal catheter fluid which, in turn, transmits the pressure to the device.

External Data Receiver

The External Data receiver contains a specific RF antennae which receives the signals from the transmitter. The data from the device is received and recorded for physician use. The external receiver does not process the data or make any data calculations.

The external unit is powered by the Power Supply.

Analog Adapter

The Analog Adapter is an interface between the single channel transmitter and external analog recording instruments. The Analog Adapter along with the Ambient Pressure Reference discussed below, provide a calibrated analog signal allowing easy connection to most computerized data acquisition systems or strip chart recorders.

Ambient Pressure Reference

The Ambient Pressure Reference component of the system provides continuous measurement of ambient barometric pressure. Continuous patient blood pressure is the difference between the pressure measured by the device and the ambient barometric pressure in the room.

External Power Supply

The power supply is a 110 VAC adapter that plugs into a standard outlet and connects to the receiver. The power supply is rated at 110 VAC and 60 Hz. It has been designed to meet UL and CSA requirements.

Signal Detector

The signal detector is a device that can be used by the physician as a tool to determine if the device is operating or in standby mode. The transmitter operates at a specific frequency range that is detected by the signal detector. If the signal is detected, the signal detector emits an audible tone.

Materials

All materials used in the manufacture of the DSI system are biocompatible and have been used in numerous previously cleared products.

Summary of Substantial Equivalence

The Blood Pressure Measurement System offers the physician a means to monitor the intra-vascular pressure at specific locations determined by the physician during and after surgery.

The DSI system is equivalent to the Millar Mikro-Tip pressure measuring catheter systems. The catheter is placed in the vasculature and measures the intra-vascular pressure. The data is monitored and recorded on an external unit. The clinical indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. DSI believes the Blood Pressure Measurement System is substantially equivalent to existing marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 1998

Mr. Jim Huhn
Data Sciences International, Inc.
4211 Lexington Avenue North
St. Paul, MN 55126-6164

Re: K971616
Blood Pressure Measurement System (DSPM 70)
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: August 20, 1998
Received: August 21, 1998

Dear Mr. Huhn:

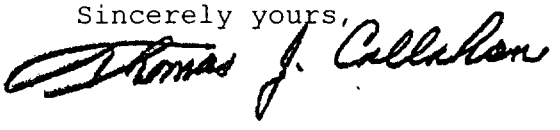
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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/dsma/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

K971616

Indications for Use

510(k) Number (if known): K971616

Device Name: Blood Pressure Measurement System

Model Number: DSPM 70

Indications for Use: The DSPM-70 Blood Pressure Measurement System is suitable for measurement of real-time blood pressure data wherever indwelling blood pressure catheters and transducers are currently used for management of intra-operative and post-surgical critically ill patients. The information measured is suitable for use in derivation of blood pressure parameters such as heart rate, systolic pressure, diastolic pressure, and mean pressure.

Not to be used where there is the potential for accidental entry of the catheter into the heart or other site in the body where patient safety may be compromised.

(continued on next page)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Wrane

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number ____

(Optional Format 1-2-96)

The transmitter portion of the product is intended to be secured to the skin with tape with the distal tip of the pressure sensing catheter placed in the vasculature at a physician specified site.

The system is intended to be limited to use in a single patient for less than 7 days. The external equipment may be reused.

While the DSPM-70 is indicated for 7 days use, research has shown that in some patient populations, risk of infection increases when indwelling catheters remain in use for longer than 72 hours. Duration of use should be determined by institutional guidelines and consideration of various sources of risk to the patient.

The DSPM-70 has no feature that provides the ability to draw blood from the patient.

[4 French models:]

Intended for use on critically ill intra-operative and post-surgical patients at sites suitable for insertion of a 4 French intravascular catheter under intensive nursing and physician care. Use an introducer sheath with an inside diameter of 0.061 inches such as the Terumo Medical model SR-OX1451CA 14 Ga x 2 inch Surflo I.V. Catheter. Introducer sheath should remain in place after insertion.

Not intended for neonatal use.

[2 French models:]

Intended for use on critically ill intra-operative and post-surgical patients at sites suitable for insertion of a 2 French intravascular catheter under intensive nursing and physician care. Use an introducer sheath with an inside diameter of 0.034 inches such as the Terumo Medical model SR-OX1832CA 18 Ga x 1 ¼ inch Surflo I.V. Catheter. Introducer sheath should remain in place after insertion.

Neonatal applications are limited to femoral artery use only.

[Additional on 4 French models over 15 cm long and 2 French models over 8 cm long. Warning appears on both package insert and on sterile package:]

Warning: Do not insert beyond mark on the catheter to prevent accidental entry of the catheter into organs where entry of the catheter into the organ may compromise patient safety.

Notice: This system includes about 0.2 seconds of time delay in the electronics which may be a factor when compared to an instantaneous device with no time delay.

Williams