OCT 2 3 2002

K020285

510(k) Summary
for
CMA Cerebral Tissue Monitoring System

1. SPONSOR

CMA/Microdialysis AB
Box 2, SE-171
18 Solna
Sweden

Contact Person: Robert Pelletier, General Manager, US Operations
Telephone: 978-251-1940, ext. 23

Date Prepared: October 21, 2002

2. DEVICE NAME

Proprietary Name: CMA Cerebral Tissue Monitoring System
Common/Usual Name: Brain Ischemia/Hypoxia Monitoring System
Classification Name: Intracranial Pressure Monitoring Device

3. PREDICATE DEVICE

- K002765, LICOX Brain Oxygen Monitoring system, CMP® Monitor and IMC® Systems
- K980380, CODMAN Neurotrend Multiparameter Sensor

4. INTENDED USE

The CMA Cerebral Tissue Monitoring System measures intracranial glucose, lactate, and pyruvate levels and is intended as an adjunct monitor of trends in these parameters indicating the perfusion status of cerebral tissue local to catheter placement. Because the CMA System values are relative within an individual, these should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide additional data to that obtained by current clinical practice in cases where ischemia or hypoxia is a concern.

5. DEVICE DESCRIPTION

The CMA Cerebral Tissue Monitoring System utilizes the principles of "microdialysis," to monitor biochemical markers of ischemia in the brain. The system consists of the following components:

- CMA 70 Brain Microdialysis Catheters
- CMA 106 Pump and Syringe
- Perfusion Fluid CNS
- Microvials and Microvial Racks
- CMA 600 Microdialysis Analyser and software
- Reagents (lactate, pyruvate, glucose)
- Control Samples
- Rinsing Fluid
- Calibrator A

The *CMA 70 Brain Microdialysis Catheter* mimics the function of a blood capillary. Molecules in the interstitial fluid diffuse over the sterile, semipermeable dialysis membrane of the catheter into the *Perfusion Fluid*, which is pumped by the *CMA 106 Microdialysis Pump*. The Perfusion Fluid equilibrates with the surrounding interstitial fluid and is collected in *microvials* at the outlet of the catheter. The microvials are changed regularly by the appropriate hospital staff and brought to the *CMA 600 Microdialysis Analyser*. The dialysate is analyzed for the concentrations of glucose, lactate and pyruvate, which are well-known markers of tissue ischemia. The data are displayed as trend curves on the screen of the CMA 600 showing the local changes in the hypoxic/ischemic state of the brain tissue.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The CMA Cerebral Tissue Monitoring System is substantially equivalent to the LICOX Brain Oxygen Monitoring system, CMP® Monitor and IMC® Systems, manufactured by Integra NeuroSciences and cleared for marketing under K002765, and the CODMAN Neurotrend Multiparameter Sensor, manufactured by Diametrics, Inc. and cleared for marketing under K980380.

The CMA, LICOX and CODMAN Systems are all intended to monitor trends in intracranial parameters to provide adjunctive diagnostic information for patients in whom hypoxia or ischemia are a concern. The CMA system assesses biochemical

markers of ischemia while the predicate devices measure pO_2, pCO_2, pH and tissue temperature. However, numerous clinical studies have been conducted to demonstrate the correlations between these measures and their safety and effectiveness in a multimodal approach to monitoring brain injured patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2002

CMA Microdialysis AB
c/o Ms. Sheila Hemeon-Heyer
Medical Device Consultants Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K020285
Trade/Device Name: CMA Cerebral Tissue Monitoring System
Regulation Number: 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: July 24, 2002
Received: July 25, 2002

Dear Ms. Hemeon-Heyer:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020285

Device Name: CMA Cerebral Tissue Monitoring System

Indications for Use:

The CMA Cerebral Tissue Monitoring System measures intracranial glucose, lactate, and pyruvate levels and is intended as an adjunct monitor of trends in these parameters indicating the perfusion status of cerebral tissue local to catheter placement. Because the CMA System values are relative within an individual, these should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide additional data to that obtained by current clinical practice in cases where ischemia or hypoxia is a concern.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020285

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

(Optional Format 1-2-96)