K071984

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510(k) Summary
for
CMA Cerebral Tissue Monitoring System

JUN 27 2008

1. Submitters name and address

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

2. Contact person and telephone number

U.S. official correspondent: Ms Nancy Blanco,
General Manager, CMA/Microdialysis Inc.
Telephone: 978-251-1940, ext. 30

Contact Person for this submission: Mr. Mats Premfors
Quality & Regulatory Affairs Manager, CMA/Microdialysis AB,
Telephone: (011) 46 8 470 1080

3. Date Prepared

June 26th, 2007

4. Device name and classification

Proprietary Name:	CMA Cerebral Tissue Monitoring System
Common/Usual Name:	Brain Ischemia/Hypoxia Monitoring System
Classification Name:	Intracranial Pressure Monitoring Device,
Product code	GWM
Class	II
Regulation number	21 CFR 882.1620
Classication Panel:	Neurology Device Panel

5. Predicate device

CMA 600 Cerebral Tissue Monitoring System, K020285
CMA Cerebral Tissue Monitoring System, K060554

6. 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
- ISCUS Clinical Microdialysis Analyzer or
  CMA 600 Microdialysis Analyzer and software
- Reagents lactate, pyruvate, glucose, glycerol and glutamate
- 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, semi-permeable 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 Microdialysis Analyzer (CMA 600 or ISCUS)*. 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 analyzer showing the local changes in the hypoxic/ischemic state of the brain tissue.

7. Intended use

The CMA Cerebral Tissue Monitoring System measures intracranial glucose, lactate, pyruvate, glycerol and glutamate 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.

8. Comparison of technical characteristics

The CMA Cerebral Tissue Monitoring System is equivalent to its predicate devices in safety and effectiveness. The components of the system, as listed above, have not been changed; the two reagents glycerol and glutamate have been added. The intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

CMA Microdialysis AB
% CMA Microdialysis, Inc.
Ms. Nancy Blanco
VP & General Manager
73 Princeton Street
North Chelmsford, Massachusetts 01863

Re: K071984
Trade/Device Name: CMA Cerebral Tissue Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracraial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: June 13, 2008
Received: June 17, 2008

Dear Ms. Blanco:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5- Indications for Use Statement

510(k) Number (if known) K071984

Device Name CMA Cerebral Tissue Monitoring System

Indications for Use

The CMA Cerebral Tissue Monitoring System measures intracranial glucose, lactate, pyruvate, glycerol and glutamate 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.

Prescription Use X (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(k) Number K071984