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K060554

**510(k) Summary  
for  
CMA Cerebral Tissue Monitoring System**

**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**

February 24, 2006

**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
Classification Panel:	Neurology Device Panel

**5. Predicate device**

CMA 600 Cerebral Tissue Monitoring System, K020285

## 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)
- 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, 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.

## 8. Comparison of technical characteristics

The functionality for the CMA Cerebral Tissue Monitoring System with ISCUS is equivalent to its predicate device CMA 600 Cerebral Tissue Monitoring System (K020285) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate device and are listed on the comparison charts provided in this 510(k) submission.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 2 2006

CMA Microdialysis AB  
c/o CMA/Microdialysis, Inc.  
Ms. Nancy Blanco  
Vice President & General Manager  
73 Princeton Street  
North Chelmsford, Massachusetts 01863

Re: K060554

Trade/Device Name: CMA Cerebral Tissue Monitoring System  
Regulation Number: 21 CFR 882.1620  
Regulation Name: Intracranial pressure monitoring device  
Regulatory Class: II  
Product Code: GWM  
Dated: April 10, 2006  
Received: April 18, 2006

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 Office of Compliance at (240) 276-0115. 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

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)** K060554

**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.

Prescription Use   X   OR Over-The-Counter Use \_\_\_\_\_  
 (Part 21 CFR 801 Subpart D) (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** K060554