OCT 1 2 2004

Attachment 2

HITACHI

HITACHI MEDICAL CORPORATION
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

510(k) Summary

K042501

Submitter Information

Submitter: Hitachi Medical Corporation
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

Contact: Douglas J. Thistlethwaite
ph: (330) 425-1313
fax: (330) 425-1410

Date: September 13, 2004

Device Name

Device Name:	Optical Topography System
Trade/Proprietary Name:	ETG-4000 Optical Topography System
Common Name:	Oximeter
Classification Name:	Oximeter
Classification Number:	Sec. 870.2700

Predicate Device

Predicate Device: Hitachi ETG-100, K011320

Device Description

Function

The ETG-4000 is a device that measures relative changes in tissue concentration of oxy-hemoglobin and deoxy-hemoglobin and total hemoglobin (proportional to the level of blood) in the surface area of the cerebral cortex by beaming near-infrared light (670-1300nm) that can penetrate the body efficiently, and is absorbed by the hemoglobin in the blood.

The ETG-4000 displays the changes of overall Hemoglobin concentration in time- course graphs, 2D topography images and 3D topography images (motion images and still images) based on the data from multiple point measurements.

This is a non-invasive test that is done by contacting an array of small optical fiber tips on the surface of the scalp.

The ETG-4000 beams frequency modulated near-infrared light into the surface of the brain through several of the optical fibers. The light passes through the scalp, skull and upper layer of the cerebral cortex. The light is absorbed by the hemoglobin in the blood and is reflected back and is collected by optical fibers.

The ETG-4000 measures relative changes in tissue concentration of oxy-hemoglobin and deoxy-hemoglobin in the blood of the cerebral cortex at multiple points on the head simultaneously by utilizing the changes of light absorption.

The ETG-4000 provides data that show the activity status of the cerebral cortex by displaying the blood volume changes, hemodynamics in the brain surface, and the metabolic and circulatory status of the cerebral cortex in a time-course graphic representation of oxy-hemoglobin, deoxy-hemoglobin and total hemoglobin, 2D dynamic images and 3D dynamic images.

Device Intended Use

The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

Device Technological Characteristics

The characteristics of the ETG-4000 Optical Topography System compare substantially to the ETG-100 predicate device in materials used, technology applied, and functional methodology. Differences do not affect safety and effectiveness of the device, intended use, or application methods. The ETG-4000 operates in a manner that is substantially equivalent to the cleared predicate device and represents an enhancement of the technology of the predicate.

Safety

The ETG-4000 is a non-invasive device with no moving parts. It has been designed to comply with all applicable safety standards.

Conclusions

The ETG-4000 system has been developed and validated in accordance with design controls and applicable standards. Testing has proven that the system is safe and effective for the indicated use. Risk and hazard analysis shows that there are no new safety issues associated with this system as compared with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2004

Hitachi Medical Corporation
c/o Mr. Douglas J. Thistlethwaite
Manager of Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087

Re: K042501
Trade/Device Name: ETG-4000 Optical Topography System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 13, 2004
Received: September 14, 2004

Dear Mr. Thistlethwaite:

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,

for Miriam C. Provost

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): K042501

Device Name: ETG-4000 Optical Topography System

Indications for Use:

The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

Prescription Use X AND/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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K042501