

JUL 25 2007

FHC Corporate & Manufacturing
1101 Main Street
Bowdoin, ME 04287-7302 USA
Tel: 207-666-8190
US & Can: 800-336-2805
Fax: 207-666-8292
E-mail: fhccorp@fhc.com
www.fhc.com**510(k) SUMMARY**

- A. Submitter:** FHC, Inc., 1201 Main Street, Bowdoin, Maine 04287
Tel: 207-666-8190; Fax: 207-666-8292
- B. Contact Person:** Lee D. Margolin, MS, PhD.
- C. Date of Summary Preparation:** March 7, 2007
- D. Trade Name:** microTargeting[®] Guideline System 4000
- E. Common Name:** Intraoperative neurophysiological recording and stimulating device
- F. Classification Name:** Depth electrode (21 CFR 882.1330, Product Code GZL)
- G. Substantially Equivalent To:**
1. Axon Instruments, Inc. Guideline System 3000 (K970943; decision date: Aug. 18, 1997)
 2. Alpha Omega Neurotrek Physiological Navigation System (K993622; decision date: Jan. 24, 2000)
- H. Description:**
The microTargeting[®] Guideline 4000 is designed for intraoperative electrophysiological microelectrode recording, stimulation, data collection, analysis and storage.

The microTargeting[®] Guideline 4000 has the following advantages and features:

- Expandable recording channels to a maximum of ten
- All active channels continuously displayed
- Up to five analysis windows
- Support for simultaneous bilateral procedures
- Support for most common stereotactic systems
- Rugged, transportable design
- Continually adjustable filters minimize noise pick-up
- Isolated stimulator capable of micro- and macrostimulation
- Handheld remote controller

- Integrated electrode impedance checking
- High fidelity audio monitoring
- Portable, full photolithography inkjet printer
- Remote data monitoring capabilities over internet

I. **Intended Use:** The microTargeting® Guideline 4000 is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist to accurately position depth electrodes during functional neurosurgical procedures.

J. **Technological Characteristics:** The technological characteristics of the microTargeting® Guideline System 4000 are the same as those in the predicate devices. There is no new technology, materials or method of manufacture introduced. Specifications in every category are either the same, very similar, or improved.

K. **Substantial Equivalence statement:** The microTargeting® Guideline 4000 is substantially equivalent to the predicate devices in design, construction, materials, intended use and performance characteristics. Non-clinical review of the device shows the device meets similar performance specifications as the predicate devices. No new issues of safety or effectiveness are introduced in the use of this device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FHC, Inc.
% Intertek Testing Services
2307 East Aurora Road
Unit B7
Twinsburg, Ohio 44087
ATTN: Daniel W. Lehtonen or Jay Y. Kogoma

JUL 25 2007

Re: K071364
Trade/Device Name: microTargeting Guideline 4000
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: July 18, 2007
Received: July 19, 2007

Dear Mr. Lehtonen or Mr. Kogoma:

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

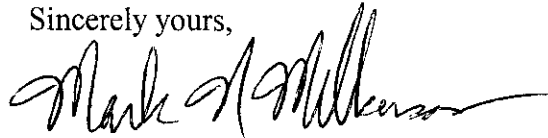
Page 2 – Mr. Daniel W. Lehtonen or Mr. Jay Y. Kogoma

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) 276-0120. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

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

Enclosure

510(k) Number (if known): _____

Device Name: microTargeting® Guideline 4000

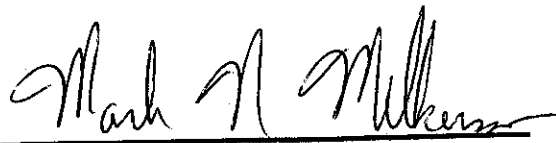
Indications For Use:

The microTargeting® Guideline 4000 system is intended to assist in functional neurosurgical procedures where recording from and stimulation of brain motor and sensory neurons will aid in the placement of depth electrodes.

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)



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

510(k) Number K071369

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