MAR 2 4 2004

K033193

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1. *Submitter's Name:*	FHC, Inc.
2. *Address:*	9 Main Street Bowdoinham, ME 04008
3. *Telephone Number:*	207-666-8190
4. *Contact Person:*	Frederick Haer
5. *Date Prepared:*	September 15, 2003
6. *Registration Number:*	1226598

B. Device

1. *Name:*	microTargeting® Electrode
2. *Trade Name:*	microTargeting® Electrode
3. *Common Name:*	Depth Electrode
4. *Classification Name:*	Depth Electrode
5. *Product Code:*	84 GZL
6. *Class:*	II
7. *Regulation Number:*	882.1330

K033173

C. Identification of Legally Marketed Devices

Name	*K Number*	*Date Cleared*
FHC microTargeting® Electrodes	K991522	Aug. 4, 2000
Radionics Semi-Microelectrode (SME) Kit	K961858	Aug. 7, 1996
Microrecording Systems Consultants µEEG Pro System 5000	K991077	June 9, 2000

D. Description of Device

The FHC microTargeting® Electrode is for intra-operative single unit recording and stimulation during functional neurosurgery.

microTargeting® Electrode Components

- Electrodes
- Protective Tube

microTargeting® Electrode Accessories

- Sterilization Tray

E. Intended Use Statement

The FHC microTargeting® Electrode is intended for use in intra-operative recording of single unit neuronal activity or intra-operative stimulation of neural elements in the brain.

F. Technological Characteristics Summary

The FHC microTargeting® Electrodes are substantially equivalent to the legally marketed FHC microTargeting® Electrodes (K991522), Radionics Semi-Microelectrode (SME) Kit (K961858), and Microrecording Systems Consultants µEEG Pro System 5000 (K991077).

Differences that exist between these devices, relating to technical specifications, physical appearance, and design do not affect the relative safety and effectiveness of the microTargeting® Electrodes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2004

Mr. Frederick Haer
President/CEO
FHC, Inc.
9 Main Street
Bowdoinham, Maine 04008

Re: K033173
Trade/Device Name: microTargeting® Electrode
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth electrode
Regulatory Class: II
Product Code: GZL
Dated: March 2, 2004
Received: March 3, 2004

Dear Mr. Haer:

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 (301) 594-4659. 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

Indications for Use
{PRIVATE }

510(k) Number (if known): K033173

Device Name: microTargeting® Electrodes

Indications For Use:

The FHC microTargeting® Electrodes are intended for use in intra-operative recording of single unit neuronal activity or intra-operative stimulation of neural elements in the brain.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K033173