3.

FHC, Inc. Frederick Haer & Co.
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AUG 4 2000

K991522
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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:*	207-666-8190
4. *Contact Person:*	Frederick Haer
5. *Date Prepared:*	July 12, 2000
6. *Registration Number:*	Not yet applied for

B. Device

1. *Name:*	microTargeting™ Electrodes
2. *Trade Name:*	microTargeting™ Electrodes
3. *Common Name:*	Depth Electrode
4. *Classification Name:*	Depth Electrode
5. *Product Code:*	84 GZL
6. *Class:*	II
7 *Regulation Number:*	Not yet applied for

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C. Identification of Legally Marketed Devices

1.	*Name:*	µEEG ProSystem 5000 Depth Electrode	Pali-Trode	Radionics SME
2.	*K Number:*	K991077	K981015	K961858
3.	*Date Cleared:*	June 9, 1999	June 16, 1998	August 7, 1996

D. Description of the Device

The microTargeting™ Electrodes (K991522) are for intra-operative single-unit recording during functional neurosurgery.

microTargeting™ Electrodes Components

- Electrodes
- Protective Tube (Shielded)

microTargeting™ Electrodes Accessories

- Sterilizable Case (E5-75)

E. Intended Use Statement

The microTargeting™ Electrodes are intended for use in intra-operative recording of single unit neuronal activity in the brain.

F. Technological Characteristics Summary

The microTargeting™ Electrodes are substantially equivalent to the Microrecording Systems Consultants µEEG ProSystem (K991077) Depth Electrode, Preferred Instruments Pali-Trode (K981015) and the Radionics SME (K961858).

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

AUG 4 2000

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

Re: K991522/S2
Trade Name: microTargeting™ Electrodes
Regulatory Class: II
Product Code: GZL
Dated: July 17, 2000
Received: July 18, 2000

Dear Mr. Hare:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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): K991522

Device Name: microTargeting™ Electrode

Indications For Use:

The microTargeting™ Electrodes are intended for use in intra-operative recording of single unit neuronal activity in the brain.

(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 Restora... Devices
510(k) Number K991522

(Optional Format 3-10-98)