DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2007

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

COPY

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

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,

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)

Mark N Milhem

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

510(k) Number K071369

Intertek ETL SEMKO

July 26, 2007

Mr. Lee Margolin
FHC Inc.
1201 Main Street
Bowdoin, ME 04287

SUBJECT: Confirmation of Market Clearance

Device Name	microTargeting Guideline 4000
Intertek Project No.	3102958
510(k) No.	K071364

Dear Mr. Lee Margolin,

This letter is to inform you that your 510(k) submission, for your device identified above has been cleared by the FDA. Enclosed is a copy of the market clearance letter and Indications for Use from FDA.

We were pleased to have been of assistance in this project.

If you have any questions please contact me e-mail at Nicole.Bartolozzi@intertek.com, phone at (330) 405-3552, or fax at (330) 405-5518.

Sincerely,

Nicole Bartolozzi

Nicole Bartolozzi
510K Administrative Assistant

Enclosures: Market Clearance Letter
Indications for Use

Intertek Testing Services NA, Inc.
2307 East Aurora Rd, Unit B7, Twinsburg, OH 44087
Telephone: 1-330-405-3552 Fax: 1-330-405-5518 Web: www.intertek-etlsemko.com