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Microelectrodes and Instrumentation for Neuroscience
Research and Clinical microTargeting®

FHC Corporate & Manufacturing
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SPECIAL 510(k) SUMMARY

Submitter: FHC, Inc., 1201 Main Street, Bowdoin, Maine 04287
Tel: 207-666-5651; Fax: 207-666-8539

Contact Person: Keri Seitz

Date of Summary Preparation: June 28, 2012

Trade Name: microTargeting™ XL STar™ Drive System

Common Name: Stereotaxic instrument

Classification Name: Stereotaxic instrument (21 CFR 882.4560, Product Code HAW)

Substantially Equivalent To: FHC, Inc. microTargeting™ STar Drive™ System K092562, September 18, 2009

Description:

When used in conjunction with commonly available stereotactic systems, the microTargeting™ XL STar™ Drive System allows a neurosurgeon to precisely position intracranial microelectrodes, stimulating electrodes, lesion electrodes and other instruments during functional neurosurgical procedures.

microTargeting™ XL STar™ Drive System Components

- microTargeting™ XL STar™ Drive
- insertion tubes
- verification probe
- sterilization case
- cleaning brushes

Device Mounting Hardware and other Components

Additional components for device mounting include hardware specifically designed to interface between the microTargeting™ XL STar™ Drive system and other stereotactic frames or instruments, and also include optional components to increase utility.

- Adapters to fit Radionics and Leksell stereotactic systems
- microTargeting controller firmware based on user specifications of drive travel.

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Intended Use:

The FHC microTargeting™ XL STar™ Drive System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system

Technological Characteristics:

Comparison Table

Parameter	microTargeting™ STar Drive™	microTargeting™ XL STar™ Drive
Indications for Use	Accurate positioning of probes in the brain or nervous system	Same
Drive mechanism	Manual and/or optional motor drive	Same
Biocompatibility		
Drive system & Accessories	No contact with tissue	Same
Insertion Tubes	304 stainless steel	Same
Travel	50 mm	Maximum of 125mm
Sterilization	Steam	Steam
Position Indicator	Manual, mechanical and/or digital readout capable	Same
Stereotactic frame adapters	Radionics, Leksell, Leibinger RM, Leibinger ZD, M-IGN NeXframe and FHC microTargeting™ Platform	Radionics and Leksell
Materials	Hardcoated Aluminum, Stainless Steel	Same

Performance testing

Performance testing of the microTargeting™ XL STar™ Drive System documented in the verification phases of design control (See Section 10 and APPENDIX C of this document) show the system to be equivalent or improved over the predicate system in ease of manufacturing, mechanical and electrical quietness, ease of use, repeatability, accuracy, rigidity, and adaptability.

Substantial Equivalence statement:

The microTargeting™ XL STar™ Drive System is substantially equivalent in design, construction, materials, intended use and performance characteristics to its predicate

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device, the FHC microTargeting™ STar Drive™ System, which was cleared under 510(k) K092562, September 18, 2009.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

FHC, Incorporated
% Ms. Keri Seitz
President and CEO
1201 Main Street
Bowdoin, Maine 04287

Re: K121950
Trade/Device Name: microTargeting™ XL STar Drive™ System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: June 28, 2012
Received: July 3, 2012

Dear Ms. Seitz:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K121950

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Indications for Use:

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(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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121950

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)