JUL 2 3 2004

K040979

ELEKTA INSTRUMENT AB

Dokumentnamn/*Name of document*
Traditional 510(k)

Utfärdare/*Issuer*	Ref nr/Dok nr/*Ref no/Doc no*	Utgåva /*Edition*
Anders Skoglund	Pd106 OEM MER MICRODRIVE FDA	1
Avser/*Regarding*		Directory
ELEKTA Microdrive		

Section 4- 510(k) Summary

As Required by 21 CFR 807.87(k)510 (k) Summary

1. Subscribers Name & Address

Elekta Instrument AB
Kungstensgatan 18, P:O Box 7593
SE-103 93 Stockholm, Sweden
Tel: (011) 46 8 587 254 00
Fax: (011) 46 8 587 255 00
Contact Person for this submission: Mr Anders Skoglund
Official Correspondent: Mr Peter Löwendahl

2. Trade Name

ELEKTA Microdrive

3. Device Classification

Common Name	Product Code	Class	Regulation Number
Stereotaxic instrument	HAW	II	21 CFR 882.4560

4. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	510(k) #
FHC Inc, MicroTargeting® Drive System	K011775
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5. Other relevant submissions

Devices	510(k) #
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6. Device Description (for detailed description see Section "Device Description")

The ELEKTA Microdrive consists of a drive which is connected to the instrument holder of the stereotactic system, the MicroGun that holds the guide tubes and the Electrode holder where the electrodes are fixed. The guide tubes are inserted into the MicroGun and fixed with the lower end of the guidetubes 11 or 21 mm (two different lengths of guide tubes exist) in front of the target point. By moving a sledge with a fine-pitch screw the electrodes are advanced through the guide tubes into the brain. It is possible to position up to five electrodes simultaneously.

7. Intended Use

The ELEKTA Microdrive is intended to be used for accurate positioning of electrodes or other devices during stereotactic neurosurgery.

8 Substantial Equivalence

The functionality for the ELEKTA Microdrive is equivalent to its predicate device the FHC Inc, MicroTargeting® Drive System (K011775) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate device and are listed on the comparison charts provided in this 510 k submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Mr. Anders Skoglund
Regulatory Affairs Engineer
Elekta Instrument AB
Kungstensgatan 18
P.O. Box 7593
SE-103 93 Stockholm
Sweden

Re: K040979
Trade/Device Name: ELEKTA Microdrive
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: June 24, 2004
Received: June 30, 2004

Dear Mr. Skoglund:

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 Mark N. Melkerson

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

Section 7- Indications for Use Statement

510(k) Number To be defined K040979

Device Name ELEKTA Microdrive

Indications for Use The ELEKTA Microdrive is intended to be used for accurate positioning of electrodes or other devices during stereotactic neurosurgery.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K040979