K041409

1 / 2

Inomed GmbH

AUG 2 0 2004

Dokumentnamn/Name of document	
Traditional 510(k)	

Utfärdare/Issuer	Ref nr/Dok nr/Ref no/Doc no	Utgåva /Edition	Sida/Page
Anders Skoglund	Pj03 017	1.0	12
Avser/Regarding: Micro - recording and stimulation electrodes		Directory	

Section 4- 510(k) Summary

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

1. Subscribers Name & Address

Inomed GmbH
Tullastraße 5a
D-79331 Teningen, Germany
Tel: (011) 49 7641 9414-0
Fax: (011) 49 7641 9414-94
Official Correspondent: Mr Alexander Thern

Contact Person for this submission:
Mr Anders Skoglund (Elekta Instrument AB, Tel: (011) 46 8 587 254 00
Fax: (011) 46 8 587 255 00)

2. Trade Name

Micro - recording and stimulation electrodes

3. Device Classification

Common Name	Product Code	Class	Regulation Number
Depth electrode	84 GZL	II	21 CFR 882.1330

4. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	510(k) #
FHC microTargeting Electrodes	K033173
--	--

5. Other relevant submissions

Devices	510(k) #
N/A	N/A

6. Device Description (for detailed description see Section "Device Description")

MicroMacroelectrodes are equipped with a micro tip and a MacroElectrode. The micro tip is used to for recording cell potentials of single cells or of cell clusters and for MicroStimulation. The macro tip is used for stimulation and recording of local field potentials.

MacroElectrodes are monopolar electrodes equipped with an active macro tip. They are used for stimulation and recording of local field potentials.

Micro Electrodes are monopolar electrodes equipped with a micro tip. They are used for recording cell potentials of single cells or cell clusters and for Microstimulation.
They are similar to MicroMacroelectrodes but without the Macroelectrode.

7. Intended Use:

The Micro - recording and stimulation electrodes is intended to be used in the human brain for the recording of Neuro potentials of single brain cells and for electrical stimulation of small areas in the brain.

8 Summary of technological characteristics of Device and Predicate Device:

The functionality for the Micro - recording and stimulation electrodes are equivalent to its predicate device the FHC Inc, microTargeting Electrode (K033173) 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

AUG 2 0 2004

Inomed GmbH
c/o Mr. Anders Skoglund
Regulatory Affairs Engineer
Elekta Instrument AB
Kungstensgatan 18, P.O. Box 7593
SE-103 93 Stockholm
Sweden

Re: K041409
Trade/Device Name: Micro-Recording and Stimulation Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth electrode
Regulatory Class: II
Product Code: GZL
Dated: July 29, 2004
Received: August 2, 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,

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 K041909
Device Name	Micro - recording and stimulation electrodes
Indications for Use	The Micro - recording and stimulation electrodes are intended to be used in the human brain for the recording of Neuro potentials of single brain cells and for electrical stimulation of small areas in the brain.

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)

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

510(k) Number K041409