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K042208

Inomed GmbH

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

Utfärdare/*Issuer*	Ref nr/Dok nr/*Ref no/Doc no*	Utgåva /*Edition*
Saschka Busch	Pj01 079	1.2
Avser/*Regarding* ISIS MER System / Elekta MER System		Directory

Section 4- 510(k) Summary

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

1. Subscribers Name & Address

Inomed Medizintechnik GmbH
Tullastrasse 5a
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Mr Anders Skoglund (Elekta Instrument AB, Tel: (011) 46 8 587 254 00
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2. Trade Names

ISIS MER System / Elekta MER System

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) #
Axon Guideline System 3000A	K970943
Keypoint / Leadpoint system	K944574

5. Other relevant submissions

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

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

During neurosurgical interventions the ISIS MER System / Elekta MER System is used for optimal target localization by extra cellular recording and deep brain stimulation.

The system operates the integrated neurostimulator that delivers impulses similar to the impulses of the DBS electrode. It is thus possible to simulate the later effect of an implanted electrode. Recording and stimulation of up to five channels are possible simultaneously. A sixth channel is reserved for the depth sensor. Free channels may be used for EMG recording for optimal patient surveillance.

7. Intended Use:

The ISIS MER System / Elekta MER System is intended to be used during neurosurgery to record and stimulate brain motor and sensory neurons to aid in the placement of depth electrodes.

8 Summary of technological characteristics of Device and Predicate Device:

The functionality for the ISIS MER System / Elekta MER System are equivalent to its predicate devices the Axon Guideline System 3000A (K970943) and the Dantec / Medtronic Keypoint / Leadpoint system (K944547) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate devices 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

MAR 18 2005

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

Re: K042208
Trade/Device Name: NeuroTrek System
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth electrode
Regulatory Class: II
Product Code: GZL
Dated: February 24, 2005
Received: February 28, 2005

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting 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 K042208
Device Name	ISIS MER System / Elekta MER System
Indications for Use	The ISIS MER System / Elekta MER System is intended to be used during neurosurgery to record and stimulate brain motor and sensory neurons to aid in the placement of depth electrodes.

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)

ivision Sign-Off)
ision of General, Restorative

(K) Number K042208