ELEKTA INSTRUMENT AB K059746

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

Utfärdare/*Issuer*	Ref nr/Dok nr/*Ref no/Doc no*	Utgåva /*Edition*
Anders Skoglund	-	1
Avser/*Regarding* Elekta Esarte™ Frame System		Directory -

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 Esarte™ Frame System

3. Device Classification

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

4. Regulatory History (Unmodified Predicate Device)

Devices	510(k) #
Leksell® Stereotactic System with disposable biobsy needle kit	K031980
Leksell® Stereotactic System with MR Post Kit	K031999
Leksell® Stereotactic System	K972324

5. Other relevant submissions

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

The Elekta Esarte™ Frame System is used in stereotactic radiation therapy (SRT) to provide target localization (spatial reference), and the fixation of the patient's head at prescribed geometric coordinates on the Precise table top of the digital accelerator. The Elekta Esarte™ Frame also attaches to the table of the CT scanner that is used to acquire images for the SRT planning.

7. Intended Use

The Elekta Esarte™ Frame System is part of Leksell Stereotactic System®, which is intended for localization and diagnosis of intracranial disorders and their surgical treatment including radiosurgery and stereotactic radiation therapy.

8 Substantial Equivalence

The functionality for the Elekta Esarte™ Frame System is equivalent to its predicate device Leksell® Stereotactic System with disposable biobsy needle kit (K031980) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2005

Mr. Peter Löwendahl
Quality and Regulatory Affairs Manager
Elekta Instrument AB
P.O. Box 7593
SE-103 93 Stockholm
SWEDEN

Re: K051746
Trade/Device Name: Elekta Esarte™ Frame System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: HAW and LHN
Dated: June 27, 2005
Received: June 29, 2005

Dear Mr. Löwendahl:

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Section 7- Indications for Use Statement

510(k) Number	To be defined
Device Name	Elekta Esarte™ Frame System
Indications for Use	The Elekta Esarte™ Frame System is part of Leksell Stereotactic System®, which is intended for localization and diagnosis of intracranial disorders and their surgical treatment including radiosurgery and stereotactic radiation therapy.

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 NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051746