K082122

AUG 29 2008

510(k) SUMMARY

Date of preparation of summary: 18th July 2008

Submitted by:
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Contact name: Mr. Patrick Hull

Trade Name: MLCi2

Common Name: Multileaf Collimator

Classification Name: Medical Linear Accelerator Accessory, IYE

Predicate Device: MLCi (K963624)

Product Description:

This Special 510(k) describes modifications to the MLCi multileaf collimator for use as an accessory for the Elekta range of medical digital linear accelerators. These modifications provide the following improvements;

- Improved x-ray performance (peak and average leakage).
- Improved repeatability of leaf edge position.
- The ability for leaves to interdigitate.

Intended Use Statement:

The MLCi2 Multileaf collimator is indicated for use when additional flexibility is required in conforming the radiation beam to the anatomy to be exposed.

Summary of Technological Characteristics:

The MLCi multileaf collimator has been modified to improve leaf design. The changes made result in the following characteristics;

- Leaf height increased by 6.5%.
- Leaf profile and attitude changed to reduce leakage.
- Leaf guidance improved to allow interdigitation.

Substantial Equivalence

The functionality for the MLCi2 is equivalent to its predicate device the MLCi (K963624) in safety and effectiveness. The fundamental technical characteristics are the same as those of the predicate device and differences in operation are described in the comparison chart and discussion provided elsewhere in this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 29 2008

Mr. Patrick T. M. Hull
Regulatory Affairs Engineer
Elekta Limited
Linac House, Fleming Way
Crawley, West Sussex RH10 9RR
UNITED KINGDOM

Re: K082122
Trade/Device Name: MLCi2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 23, 2008
Received: July 28, 2008

Dear Mr. Hull:

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Indications for Use

510(k) Number (if known): K082122

Device Name MLCi2

Indication for Use: **The MLCi2 Multileaf collimator is indicated for use when additional flexibility is required in conforming the radiation beam to the anatomy to be exposed.**

Prescription Use - YES AND/OR Over-The-Counter Use - NO

(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

(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 Reproductive, Abdominal and Radiological Devices
510(k) Number K082122