SUMMARY OF SAFETY & EFFECTIVENESS

K042794 JAN 3 1 2005

page 1 of 2

Elekta Limited hereby provides the following material summarising safety and effectiveness information for the Beam Modulator™. This information is summarised as follows: -

1. The Beam Modulator™ is an enhancement to the previously reported MLC multileaf collimator, D.C. Number K904124, and the MLCi, multileaf collimator, D.C. Number K963624. Other predicate devices are the Millennium multileaf collimator from Varian Assoc. Inc., D.C. number K990085 and the Moduleaf multileaf collimator from MRC Systems GmbH, D.C. number K030609.

   These devices have an established and proven track record for safety. The primary reason for the introduction of this product is to provide more precise conformance to desired treatment volume by providing a leaf pitch of 4 millimetres. The Beam Modulator™ does not raise additional types of safety or effectiveness considerations.

2. It is our opinion that the Beam Modulator™ does not have technological characteristics that raise additional types of safety or effectiveness questions, and that we consider it an enhancement to the previously cleared devices within the Elekta product range.

3. The accompanying documents provided for the user contain comprehensive information to ensure safe and effective use. Past experience with substantially equivalent predicate devices has shown our device to be safe and effective when used as directed by the accompanying documents provided for the user.

4. The Beam Modulator™ is subject to compliance testing as defined in the internationally recognised safety standards IEC 60601-1 and IEC 60601-2-1.

5. The Beam Modulator™ is designed to bear the CE mark affirming compliance with all relevant European Directives in force, in particular the European Medical Device Directive. As a result of this, products may be sold freely without restriction throughout the entire European Union.

6. The Elekta Limited Quality Management System has been established to satisfy the requirements of ISO 9001, ISO 13485, the Medical Device Directive 93/42/EEC Annex II and US 21 CFR 820. Elekta Limited has developed the Beam Modulator™ using an established and documented Quality Management System.

© 2004 Elekta Limited. All rights reserved

SUMMARY OF SAFETY & EFFECTIVENESS

K042794

7. Elekta Limited is a registered medical device manufacturer of assessed capability against the requirements of ISO 9001, ISO 13485 and the Medical Device Directive 93/42/EEC Annex II.

8. In accordance with the above requirements all parts of the Quality System are subject to periodic and systematic internal Quality Audits. These audits are performed by trained personnel not having direct responsibilities in the functions being audited.

9. The quality system is subject to regular, planned and documented GMP audits conducted by external auditors from SGS Yarsley (UK Notified Body) and the FDA.

10. Elekta Limited has conducted hazard analysis on the Beam Modulator™ and has concluded that it does not introduce hazards that raise new types of safety or effectiveness considerations. After considering the Guidance for the Content of Pre-Market Notification Submissions of Medical Devices Containing Software Elekta Limited has concluded the level of concern appropriate to the device is "Major".

Signature ..... Date 29 Sep 2004

Peter Hart, Vice President, Research & Development

Signature ..... Date 29.9.04

Dee Mathieson, Vice President, Product Management

Signature ..... Date 29/9/04

Mark A Osborne, Regulatory Affairs Manager

© 2004 Elekta Limited. All rights reserved

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2005

Mr. Peter Stegagno
Vice President, Regulatory Affairs
and Quality Assurance
ELEKTA Ltd.
4775 Peachtree Industrial Boulevard
Building 300, Suite 300
NORCROSS GA 30092

Re: K042794
Trade/Device Name: Elekta Beam Modulator™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: 90 IYE and IXI
Dated: January 5, 2005
Received: January 6, 2005

Dear Mr. Stegagno:

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/dsma/dsmamain.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

510(k) Number (if known): K042794

Device Name ..... Beam Modulator™

Indication for Use: The Elekta Beam Modulator is an X-ray collimator, designed to be used with the Elekta range of medical linear accelerators and intended to assist a licensed practitioner in the delivery of radiation to defined target volumes, (e.g. lesions, arterio-venous malformations, malignant and benign tumours), whilst sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fraction delivery of radiation in all areas of the body where such treatment is indicated.

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 K042794