AUG 1 4 2001

K012289

SUMMARY OF SAFETY & EFFECTIVENESS

7) Elekta Oncology Systems is a registered medical device manufacturer of assessed capability against the requirements of ISO 9001, EN 46001, 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 Oncology Systems has conducted hazard analysis on the *i*ViewGT™ EPID 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 EOS has concluded the level of concern appropriate to the device is "Higher".

Signature .....

Vice President Research & Development

Signature .....

Director Product Management

Signature .....

Vice President Quality and Regulatory Affairs Manager

SUMMARY OF SAFETY & EFFECTIVENESS

Elekta Oncology Systems Ltd hereby provide the following material summarising safety and effectiveness information for the Elekta Oncology Systems *i*ViewGT™ Electronic Portal Imaging Device(EPID). This information is summarised as follows:-

1) The *i*ViewGT™ EPID is an enhancement to the existing *i*View Electronic Portal Imaging Device which has previously been cleared for commercial distribution under D.C. K981790. These devices have an established and proven track record for safety. The primary reason for this modification to support solid state detectors for image acquisition. The *i*ViewGT™ EPID does not raise additional types of safety or effectiveness considerations.

2) It is our opinion that the *i*ViewGT™ EPID does not have technological characteristics that raise additional types of safety or effectiveness questions, and that we consider them an enhancement to the existing *i*View Electronic Portal Imaging Device.

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 *i*ViewGT™ EPID is subject to compliance testing as defined in the internationally recognised safety standards IEC 60601-1 and IEC 60601-2-1. As appropriate, proprietary information technology equipment is procured to the internationally recognised standards IEC 60950 and/or UL 1950.

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

6) Elekta Oncology Systems Software Quality System has been established to satisfy the requirements of ISO 9001, EN 46001, ISO 13485, the Medical Device Directive 93/42/EEC Annex II and the US 21 CFR 820 GMP. Elekta Oncology Systems has developed the *i*ViewGT™ EPID using an established and documented Quality Management System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2001

Elekta Oncology Systems (EOS), Ltd.
% Mr. Peter Stegagno
Director, Regulatory Affairs & Quality Assurance
Elekta Instruments, Inc.
3155 Northwoods Parkway
NORCROSS GA 30071

Re: K012289
iView GT Electronic Portal Imaging Device
Dated: July 19, 2001
Received: July 20, 2001
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Stegagno:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as Set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 592-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 592-4639. Also, please note the regulation entitled, "Misbranding by reference notification" (21CFR 807.97). Othr general information on your responsibilities under the Act may be obtained from the Division of Small Manufactures International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address http://www.da.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(s)

510(k) Number (if known): K012289

Device Name: EOS *i*ViewGT™ EPID

Indication for Use:

The EOS *i*ViewGT™ Electronic Portal Imaging Device (EPID), as with the predicate *i*View, is intended to be used with radiation therapy treatments of malignant neoplastic diseases, as determined by a licensed medical practitioner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

[redacted]
Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012289