

SUMMARY OF SAFETY & EFFECTIVENESS

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

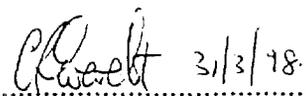
- 1) The *iView* EPID is an enhancement to the existing SRI 100 electronic portal imaging device which has previously been cleared for commercial distribution. These devices have an established and proven track record for safety. The primary reason for the introduction of this device is to address obsolescence issues associated with the image acquisition components and the computer hardware/operating system. The *iView* EPID does not raise additional types of safety or effectiveness considerations.
- 2) 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.
- 3) It is our opinion that the *iView* 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 SRI 100 electronic portal imaging device.
- 4) The *iView* EPID has been subject to compliance testing as defined in the internationally recognised safety standards IEC 601-1 and IEC 601-2-1. As appropriate, proprietary information technology equipment is procured to the internationally recognised standards IEC 950 and/or UL 1950.
- 5) All products bear the CE mark affirming compliance with all relevant European Directives in force. In particular compliance has been assured to 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 is a registered medical device manufacturer of assessed capability against the requirements of ISO 9001, EN 46001, and the Medical Device Directive, 93/42/EEC Annex II.

REF: 804/ PC52MAO7795 MO7QA078	Summary of Safety & Effectiveness Information for the Elekta Oncology Systems <i>iView</i> Electronic Portal Imaging Device (EPID)	N.C. 4513 364 1878 Attachment No: 9	
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- 7) Elekta Oncology Systems Software Quality System has been established to satisfy the requirements of ISO 9001, EN 46001, the Medical Device Directive, 93/42/EEC Annex II, and the US 21 CFR 820 GMP. Elekta Oncology Systems has developed the *iView* EPID using an established and documented Software Quality Management System.
- 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) Additionally 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 *iView* EPID and has concluded that it does not introduce hazards that raise new type of safety or effectiveness considerations and that the level of concern appropriate to the device is high.

Signature 
 Development Director

Signature 
 Field Support Director

Signature 
 Quality and Regulatory Affairs Manager

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Paul L. Sumner
Director, Regulatory Affairs
& Quality Assurance
Elekta Instruments, Inc.
8 Executive Park West
Atlanta, GA 30329Re: K981790
iView Electronic Portal Imaging Device (EPID)
Dated: May 19, 1998
Received: May 20, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Sumner:

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 indications for use stated in the enclosure) to 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 device 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) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 981790

Device Name: EOS iView Electronic Portal Imaging Device (EPID)

Indication For Use:

The EOS iView EPID, as with the predicate SRI 100, 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K 981790

Prescription Use X
(Per 21 CFR 801.109

OR Over-The-Counter Use _____