K983678

JAN 15 1999

SUMMARY OF SAFETY & EFFECTIVENESS

Elekta Oncology Systems Ltd hereby provides the following material, summarising information on the safety and effectiveness information of the Elekta Oncology Systems Prec*i*se™ Treatment Table. This information is summarised as follows:

1. The Prec*i*se™ Treatment Table is an enhancement to the previously reported EOS RAM and Pedestal devices that have been cleared for commercial distribution. These devices have established and proven track records for safety. This enhancement offers improved directional accuracy and repeatability to provide for easier and more efficient patient set up. The Prec*i*se™ Treatment Table is further considered as an enhancement to the RAM and Pedestal devices.

2. Accompanying documents provided for the user contain comprehensive information to ensure safe and effective use. Past experience with substantially equivalent predicate devices have shown them to be both safe, and effective when used as directed by such accompanying documents provided to the user.

3. It is our opinion that the Prec*i*se™ Treatment Table does not have technological characteristics that raise additional types of safety or effectiveness questions, and that we consider them an enhancement to the existing EOS RAM and Pedestal devices.

4. The Prec*i*se™ Treatment Table is subject to compliance testing as defined in the internationally recognised safety standards of IEC 60601-1 and IEC 60601-2-1.

5. The Prec*i*se™ Treatment Table is designed to bear the CE mark affirming compliance with all relevant European Directives in force, particularly the European Medical Device Directive, and the European Electromagnetic Compatibility Directive. Consequently, products may be sold freely without restriction throughout the entire European Union.

6. As the Prec*i*se™ Treatment Table contains no executable software, the design ensures "Year 2000" conformity, and additionally ensures that the integrity of "Year 2000" Conformity Compliance is not compromised for systems in which the Prec*i*se™ Treatment Table may be used.

7. 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.

K983678

8. The Quality System of Elekta Oncology Systems has been established to satisfy the requirements of ISO 9001, EN 46001, the Medical Device Directive 93/42/EEC Annex II, and 21 CFR 820. Elekta Oncology Systems has developed the Prec*i*se™ Treatment Table using this established and documented Quality Management System.

9. In accordance with the above requirements, all parts of the Quality System are subject to periodic and systematic internal Quality Audits. Trained personnel not having direct responsibilities in the functions being audited perform these audits.

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

11. Elekta Oncology Systems has conducted hazard analyses on the Prec*i*se™ Treatment Table. Although the Prec*i*se™ Treatment Table does not contain software, Elekta Oncology Systems has employed the Guidance for the Content of Pre-Market Notification Submissions of Medical Devices Containing Software and, in doing so, has concluded the level of concern appropriate to the device is "Higher".

12. It is our opinion that the device does not raise new types of safety or effectiveness considerations.

Signature .....

P.A. Hart
Vice President Research & Development

Signature .....

P.J. Gaccione
Vice President Field Support

Signature .....

M.A. Osborne
Regulatory Affairs & Standardisation Manager

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 15 1999

Paul L. Sumner
Director, Regulatory Affairs & Quality Assurance
Electra Instruments, Inc.
3155 Northwoods Parkway, NW
Norcross, GA 30071

Re: K983678
Precise™ Treatment Table
Dated: October 19, 1998
Received: October 20, 1998
Regulatory class: II
21 CFR 892.5770/Procode: 90 JAI

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 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 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,

Capt. Daniel G. Schultz, M.D.
Acting 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): K983678

Device Name: Precise™ Treatment Table

Indication for Use:

The Precise™ Treatment Table is intended as a universal patient treatment support and positioning table for radiation therapy and simulation use. It is for use with existing Elekta Linear Accelerators and Simulators and adaptable to third party radiotherapy products.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983678