K993766

DEC - 8 1999

Attachment C

510(k) Summary

Submitter: MDS Nordion
447 March Road
Kanata, Ontario K2K 1X8
CANADA

Tel: 613-592-3400 x2372
Fax: 613-592-2006

Contact Person: E. S. Martell, Vice President
Quality & Regulatory Affairs

Date Prepared: October 29, 1999

Device Name: Helax-TMS

Classification Name: Medical Charged-Particle Radiation Therapy System (892.5050)

Common or Usual Name: Radiation Therapy Treatment Planning System

Legally Marketed Predicate Device:

TMS v 3.0 (K962892) and TMS v 2.10 (K953391),
CadPlan Helios Option 6.0 (K984532)
NOMOS Peacock Plan (K940663) and identified as NOMOS CORVUS (K963258)

Description of Helax-TMS v 5.0:

Helax TMS is a 3D Radiotherapy Treatment Planning (RTP) system for radiation dose planning of patients undergoing external beam and Brachytherapy treatment in the oncology clinic. TMS is a 3-D system, using modern algorithms for dose calculations. The user has the option of selecting either a convolution/superposition pencil beam or a Collapsed Cone algorithm for photons, and a Gaussian pencil beam model for electrons. A Brachytherapy module is integrated into TMS for treatment modeling of interstitial and intracavity Brachytherapy techniques. The system software is designed to lead the user through a logical flow planning process.

Intended use of Helax-TMS v 5.0:

Helax-TMS is a 3D radiotherapy treatment planning system for radiation dose planning, but not treatment, of patients undergoing external beam or Brachytherapy treatment in the Oncology clinic. The system is designed to lead the user through a logical flow planning process.

Based on quality assured radiation therapy input data Helax-TMS is used to plan radiation treatments with:

(i) linear accelerators with X-ray energies from 4 to 50MV and electron energies from 4 to 50MeV as well as cobalt-60 units. Helax-TMS will plan 3D radiotherapy treatment approaches of combined modality plans, asymmetric and non-coplanar fields; total body irradiation; multi-leaf collimators; motorised and dynamic wedges; customised blocking; compensating filters; and bolus.

(ii) Brachytherapy units for patients undergoing interstitial or intracavitary treatment in the Oncology clinic.

Export capabilities exists as part of Helax-TMS to verify beam and patient data, dose planning results, and provide on-line information to block-cutting devices and milling machines, multi-leaf collimator control units, as well as record and verify systems.

Technological Characteristics

The Helax-TMS v 5.0 is a modification of the TMS v 3.0/v 2.10 Radiation Therapy Treatment Planning System. These modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device. There are no differences between the Helax TMS v 5.0 and TMS v 3.0/v 2.10 that adversely affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 1999

E. S. Martell
Vice President
Quality & Regulatory Affairs
MDS Nordion
447 March Road
Kanata, Ontario K2K 1X8
CANADA

Re: K993766
Helax-TMS V5.0
Dated: November 4, 1999
Received: November 8, 1999
Regulatory class: II
21 CFR 892.5900/Procode: 90 MVJ

Dear Mr. Martell:

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): K993766

DEVICE NAME: HELAX-TMS V5.0

INDICATIONS FOR USE:

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(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-

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993766