JUN 6 2002

K020971
1 of 2

Section 1

510(k) Summary

1.1 Submitter:

MDS Nordion
447 March Road
Ottawa, Ontario K2K 1X8
CANADA

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

Contact Person:

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

1.2 Device Manufacturer:

MDS Nordion AB
Box 1704
SE-75147 Uppsala
SWEDEN

1.3 Device Name: DCM 2.0

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

1.5 Common or Usual Name: Radiation Therapy Treatment Planning System

1.6 Legally Marketed Predicate Device:

Helax-TMS v 5.1 (K010682) and DCM 1.0 (K011246)

1.7 Description of Dose Calculation Module (DCM):

DCM 2.0 is intended for calculations of dose plans, the calculations are based on DICOM objects and other information conveyed by a control communication protocol from the THERAPLAN treatment planning system.

1.8 Intended use of DCM:

DCM is a three-dimensional radiotherapy dose engine for radiation dose planning of patients undergoing external beam treatment in the oncology clinic.

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Based on quality assured radiation therapy input data Dose Calculation Module (DCM) is used to plan radiation treatment with:

- Linear accelerators with X-ray energies from 4 to 50MV and electron energies from 6 to 25 MeV
- Cobalt-60 units

DCM will calculate dose for 3D radiotherapy treatment approaches of combined modality plans, asymmetric and non-coplanar fields; total body irradiation; multi-leaf collimators; motorized and dynamic wedges; customized blocking and bolus.

Note: This intended use is a direct subset of the Intended Use of the predicate device, DCM with the addition of electron dose calculations for electron beams from 6 to 25 MeV.

1.9 Technological Characteristics

DCM 2.0 has the same technological characteristics as DCM 1.0 and introduces the capability of performing electron calculations using the Voxel Monte Carlo, (VCM++) algorithm, supported by the electron Beam Model, EBM.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 2002

MDS Nordion AB
% Mr. E. S. Martell
Vice President, Quality
& Regulatory Affairs
MDS Nordion
447 March Road
Kanata, Ontario
CANADA K2K1X8

Re: K020971
Trade/Device Name: DCM 2.0
Radiation Therapy Treatment Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: March 20, 2002
Received: March 26, 2002

Dear Mr. Martell:

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 (PMA), it may be subject to 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

Section 12

Indications for Use

510 (k) Number: K020971

Device Name: DCM version 2.0

Indications For Use:

DCM is a three-dimensional radiotherapy dose engine for radiation dose planning of patients undergoing external beam treatment in oncology clinic.

Based on quality assured radiation therapy input data Dose Calculation Module is used to plan radiation treatment with:

- Linear accelerators with X-ray energies from 4 to 50MV and electron energies from 6 to 25 MeV
- Cobalt-60 units

DCM will calculate dose for 3D radiotherapy treatment approaches of combined modality plans, asymmetric and non-coplanar fields; total body irradiation; multi-leaf collimators; motorized and dynamic wedges; customized blocking and bolus.

David A. Segan

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020971

(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)