SEP 2 6 2003

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K032684 page 1 of 2

MDS Nordion
Science Advancing Health

Section 2.0

510(k) Summary
Prepared August 25, 2003

2.1 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

2.2 Device Manufacturer:

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

2.3 Device Name: Raycell™

2.4 Classification Name: Blood irradiators have not been classified

2.5 Common or Usual Name: Cabinet X-Ray System

2.6 Legally Marketed Predicate Device:

RS 3000 Shielded Cabinet X-Ray Blood Irradiator (K974210), see Appendix 1 for RS 3000 510(k) Notification.

2.7 Description of Device:

The Raycell Shielded Cabinet X-ray System consists of a sample holder (canister) between the two (2) x-ray tubes, dual power supplies, radiation shielding, control electronics, cooling assemblies and operator controls. The radiation source of the Raycell™ Shielded Cabinet X-ray System includes of two vertically opposed x-ray tubes contained in a shielded enclosure. It is identical to the predicate device with the exception of labeling changes to reflect the new product name and identify MDS Nordion as the manufacturer.

2.8 Intended Use of Device:

The Raycell™ Shielded Cabinet X-ray System is intended for the irradiation of blood and blood products packaged in transfusion bags when irradiation to reduce the risk of Graft versus Host Disease is indicated, and is used in accordance with "Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products" (22 July 1993 memorandum from Acting Director, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA to all registered blood establishments).

2.9 Summary of Technological Characteristics:

The Raycell is substantially equivalent to the RS 3000 (K974210). Both are indicated for the irradiation of blood and blood products to reduce the risk of transfusion-associated graft-versus-host disease in recipients at risk of this complication. MDS Nordion has not made any modifications to the RS 3000, with the exception of labeling changes to reflect the new name of the device "Raycell" and MDS Nordion as the manufacturer. The significant technological characteristics of the two devices are as follows:

Technological Characteristics	RS 3000	Raycell
Source	160 kVdc x-rays	Same
Beam filtration	0.38 mm copper	Same
Single beam HVL, water	Approximately 4 mm	Same
Dose rate	3 Gy min^{-1}	Same
Max/min dose ratio	<1.3	Same
Sample holder	Fixed, presents maximum width, minimum depth	Same
Radiation Safety	Pb shielding, interlocks	Same

2.10 Safety and Effectiveness:

The Raycell is the same as the RS 3000 with the labeling changes to reflect the new device name and manufacturer. These labeling changes do not introduce new safety and effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2003

A. Warbick-Cerone
Director, Regulatory Affairs
MDS Nordion
447 March Road
Ottawa, Ontario K2K 1X8
CANADA

Re: K032684
Trade/Device Name: Raycell™, Catalog Number - GR2
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 90 MOT
Dated: August 25, 2003
Received: August 29, 2003

Dear Ms. Warbick-Cerone:

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 Section 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 the 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" (21CFR Part 807.97) you may obtain. 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 1.0

Indication for Use

510 (k) Number: K032684

Device Name: Raycell™

Indications For Use:

The Raycell™ Cabinet X-ray System is intended for the irradiation of blood and blood products packaged in transfusion bags when irradiation to reduce the risk of Graft versus Host Disease is indicated, and is used in accordance with "Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products" (22 July 1993 memorandum from Acting Director, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA to all registered blood establishments).

(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,
and Radiological Devices
510(k) Number K032684