K090182

NUCLEMED

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510(K) SUMMARY

MAY - 4 2009

MIRS ™

Date: December 8th, 2008

Submitter:
Nuclemed S.A.
V. Arredondo 2684 - 2ª Piso
1426 Buenos Aires - Argentina
Phone: (54) 11 4896-0989

Contact Person:
Raymond J Kelly IV
Arazy Group
56B Shadowbrook, Dr Hudson, NH 03051
Phone: (603) 595-0095
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Device Names:

Trade Name: *MIRS ™ Module Integrated Radiotherapy System*
Common Name: *Module Integrated Radiotherapy System*
Classification Name: *System, Planning, Radiation Therapy Treatment*

Legally Marketed Device to Which Substantial Equivalence is Claimed:

The MIRS ™ unit is substantially equivalent (SE) to Rad Calc (K010464) cleared in 2001, CDMS (K082606) cleared in 2008, PLATO SRS (K010784) cleared in 2001, FOCUS SRS (K973936 + K002147) cleared in 1998, IMSure (K031975) cleared in 2000, ERGO++ (K080601) cleared in 2008, ADAC Pinnacle3 (K951581) cleared in 1996, Pinnacle3 (K993923) cleared in 2000, and the FOCUS RTP (K915691) cleared in 1995.

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510(K) SUMMARY (CONTINUED)

MIRS ™

Device Description:

MIRS ™ is used to create treatment plans for patients for whom external beam radiation therapy has been prescribed. The system will calculate and display three dimensional radiation dose distributions within the patient for a given treatment plan set up. MIRS (Module Integrated Radiotherapy System) is a modular three dimensional treatment planning system for different treatment modalities of radiation therapy, from conventional radiotherapy to Conformal Radiation Therapy, Intensity Modulated Radiation Therapy and Radiosurgery with Conic Collimators. MIRS supports any stereotactic frame. MIRS has automatic multimodality image registration, with and without fiducials. Besides 3D RMI and CT images studies with any orientation (axial, coronal or sagital), MIRS supports registration of functional RMI, PET and angiography.

Intended Use:

MIRS ™ is used to create treatment plans for patients for whom radiation therapy has been prescribed. The system will calculate and display three dimensional radiation dose distributions within the patient for a given treatment plan set up. MIRS can be used for different treatment modalities of radiation therapy, as conventional therapy, Conformal Radiation Therapy, Intensity Modulated Radiation Therapy, and Radiosurgery with Conic Collimators.

Technological Characteristics Comparison to Predicate Device:

The proposed device was compared to the predicate devices as described in section 9 of this submission. All of the items contained in the tables of section 9 have been found to be substantially equivalent.

Performance Data:

The proposed device's performance was compared to the predicate device's performance as described in section 10 of this submission. All of the items contained in the tables of section 10 have been found to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2009

Nuclemed S.A.
% Mr. Raymond Kelly
Senior Consultant
Arazy Group, Medes Argentina
56B Shadowbrook Dr.
HUDSON NH 03051

Re: K090182
Trade/Device Name: MIRS™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: January 15, 2009
Received: February 3, 2009

Dear Mr. Kelly:

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

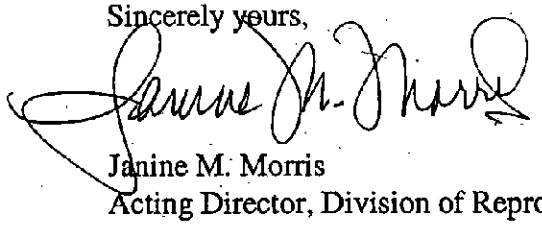
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K090182

Device Name: MIRS™

Indications For Use:

MIRS ™ is used to create treatment plans for patients for whom radiation therapy has been prescribed. The system will calculate and display three dimensional radiation dose distributions within the patient for a given treatment plan set up. MIRS can be used for different treatment modalities of radiation therapy, as conventional therapy, Conformal Radiation Therapy, Intensity Modulated Radiation Therapy, and Radiosurgery with Conic Collimators.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 and Radiological Devices
510(k) Number K090182