Rotating Gamma System Infini™

MAR 2 2 2011

510(k) Summary

This summary of Special 510(k) safety and Effectiveness information is being submitted in accordance with the requirement of SMDA1990 and 21 CFR807.92.

The assigned 510(k) number is: K102533

Submitter's Identification: MASEP Medical Science & Technology Development (Shenzhen) Co., Ltd.

Submitter's Addresses: 601, 14th Building, Software Yard, Tech Mid Road 2nd, High-Tech Zone, 518057 Shenzhen, P.R. China

Date Summary Prepared: January 11, 2011

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Http://www.masepinfini.com

Name of Device: Rotating Gamma System Infini™

Classification: Radionuclide Radiation Therapy System

The Radiology Panel of DRAED has classified this radiology therapeutic device as Class II, Performance Standards, 21 CFR Part 892.5760, Radionuclide Radiation Therapy System, Product Code 90IWB.

Predicate Device Information: The Rotating Gamma System Infini™ is substantially equivalent to the Gamma Therapy System (K#041125), manufactured and marketed by MASEP Medical Science & Technology Development (Shenzhen) Co., Ltd. and the Leksell Gamma Knife ® Perfexion™ (K#061941), manufactured and marketed by Elekta Instruments AB for treating intracranial disease. The equivalence is based on the intended use, performance specifications, materials and technology characteristics.

Device Description:

The Rotating Gamma System Infini™ is a teletherapy device indicated for use in stereotactic irradiation of intracranial structures. The system is composed of four parts:

- ^{60}Co Radiation sources
- Main unit (including mechanical system and electric system)
- Stereotactic system
- Treatment planning system

Intended Use:

The Rotating Gamma System Infini™ is a teletherapy device indicated for use in stereotactic irradiation of intracranial structures

Technical Characteristics Comparison with MASEP Predicate Device:

The Rotating Gamma System Infini ™ is an improvement of the MASEP Gamma Therapy System for which MASEP was cleared under K041125. All safety and effectiveness testing (including risk analysis and pertinent performance testing) were conducted and completed with passing results.

Infini ™ has the following modifications:

- Change in treatment bed movement.

  MASEP Gamma Therapy System: Bed only moves in Z axis;

  Infini™: Bed moves in 3 dimensions (X, Y and Z axis).

- Change in collimator diameter sizes

  MASEP Gamma Therapy System: Φ4 mm, Φ8 mm, Φ14 mm, Φ18 mm, Φ22 mm, total of 5 sizes

  Infini™: Φ4 mm, Φ8 mm, Φ14 mm, Φ18 mm, total of 4 sizes eliminating Φ22 mm collimator.

- Change in number of ^{60}Co radioactive sources and total initial loading activity

  MASEP Gamma Therapy System: number of ^{60}Co radioactive sources = 25, total initial loading ≥ 6500 Ci.

  Infini™: number of ^{60}Co radioactive sources = 30, total initial loading ≥ 7800 Ci.

- Change in radioactive source switching design

  MASEP Gamma Therapy System: Through rotation of the switching body, collimator passage is opened thus permitting passage of radiation. Likewise through reverse rotation of switching body, collimator passage is blocked thus closing radiation passage.

  Infini ™: Through rotation of the 6 switching valves, collimator passage is opened thus permitting passage of radiation. Likewise through reverse rotation of 6 switching valves, collimator passage is blocked thus closing radiation passage.

For all design changes, a risk analysis and safety and effectiveness testing were performed. All testing that was conducted showed passing results.

Comparison to Predicate Device:

Both the Infini™ and the Gamma Therapy System devices (K041125) are intended for stereotactic irradiation of intra-cranial structures. Infini™ can perform the same function as realized by the Gamma Therapy System (K041125).

The performance of the subject Rotating Gamma System Infini™ is similar in both geometric accuracy and dosimetric characteristics to the predicate device, with other similar technological characteristics.

Equivalencies include: same principle, intended use, energy used or transmitted, materials, similar design and operations. Similarities are reflected in safety, effectiveness, labeling, compatibility, standards, and application characteristics.

Discussion of Non-Clinical Testing Performed for Determination of Substantial Equivalence:

Non-clinical testing was conducted to validate and verify that the Rotating Gamma System Infini™ met all design specifications and is substantially equivalent to the predicate device.

Rotating Gamma System Infini™ has also been tested to assure compliance to the requirements of various published standards, including IEC60601-1, IEC60601-2, ISO14971 and ISO 2919. Performance testing, including software validation testing to a major level of software concern for the Rotating Gamma System Infini™ device, was conducted to verify that the operation of the entire Infini™ system along with its electrical control system has not been adversely affected by the device modifications.

Conclusion:

The Rotating Gamma System Infini™ has the same intended use and similar characteristics as the predicate devices. Testing demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. The Rotating Gamma System Infini™ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MASEP Medical Science & Technology Development (Shenzhen) Co., Ltd.
% Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Boulevard, Suite 200
GREAT NECK NY 11021

MAR 2 2 2011

Re: K102533
Trade/Device Name: Rotating Gamma System Infini™ (Infini™)
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB, MUJ
Dated: March 14, 2011
Received: March 16, 2011

Dear Ms. Goldstein-Falk:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Rotating Gamma System Infini™

Indications for Use Statement

510(k) Number (if known): K102533

Device Name: **Rotating Gamma System Infini™ (Infini™)**

Indications for Use:

The Rotating Gamma System Infini™ (Infini™) is a teletherapy device indicated for use in stereotactic irradiation of intracranial structures.

Prescription Use _X_ AND/OR Over-The Counter Use____

(Part 21 CFR 801 Subpart D) (21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

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