K063382

DEC 26 2006

Appendix 1

510(k) Summary

K063382

Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act

November 2, 2006

1. General Provisions

Common/Usual Name: Remote Controlled Radionuclide Applicator System

Proprietary Name: HDR CT Compatible Split Ring Applicator

Applicant Name and Address:

Mick Radio-Nuclear Instruments, Inc.
521 Homestead Avenue
Mount Vernon, New York 10550

2. Name of Predicate Devices:

(1)

Device	Manufacturer	K Number
CT HDR Tandem / Ring Applicator with Rectal Retractor	Mick Radio-Nuclear Instruments, Inc.	K030110
HDR Tandem/Ring Applicator with Rectal Retractor	Mick Radio-Nuclear Instruments, Inc	K011657
H.A.M. Applicator	Mick Radio-Nuclear Instruments, Inc	K961601

[1] Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "...a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seg. (1977).

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3. Classification

This device is classified as a class II device according to 21 CFR 892.5700 .

4. Performance Standards

Performance standards for applicators for remote controlled afterloading brachytherapy have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description

The HDR CT Compatible Split Ring Applicator presented in this 510(k) notification has been developed to function for the positioning of HDR Remote After-Loader sealed sources in the treatment of cancer of the cervix or uterus. The design of these systems is similar to that of the predicate devices listed below.

Device	Manufacturer	K Number
CT HDR Tandem / Ring Applicator with Rectal Retractor	Mick Radio-Nuclear Instruments, Inc.	K030110
HDR Tandem/Ring Applicator with Rectal Retractor	Mick Radio-Nuclear Instruments, Inc	K011657
H.A.M. Applicator	Mick Radio-Nuclear Instruments, Inc	K961601

The delivery of radiation therapy via high dose rate Brachytherapy treatment of the cervix or uterus requires not only a stable system for precise dosimetry but also a reproducible and predictable geometry for positioning of the radioactive source under remote control. The HDR CT Compatible Split Ring Applicator is designed to act as such a device.

6. Biocompatibility

No new issues of biocompatibility are raised with regard to this device.

7. Summary of Substantial Equivalence

This device is similar in design and construction, utilizes the identical materials, and has the same intended use and performance characteristics to the predicate devices. No new issues of safety or effectiveness are introduced by using this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2007

Mr. Felix Mick
President
Mick Radio-Nuclear Instruments, Inc.
521 Homestead Avenue
MOUNT VERNON NY 10550

Re: K063382
Trade/Device Name: HDR CT Compatible Split Ring Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: November 2, 2006
Received: November 8, 2006

Dear Mr. Mick:

This letter corrects our substantially equivalent letter of December 26, 2006.

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 (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.

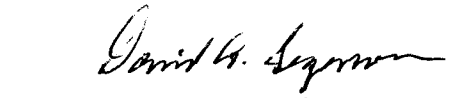
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 continue 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 (240) 276-0120. 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 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/dsma/dsmamain.html

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number: *To be assigned* K063382

Device Name: HDR CT Compatible Split Ring Applicator

Indications for Use:

The HDR CT Compatible Split Ring type applicator is indicated for use in any case where high dose rate (HDR) radiation treatment of cancer in the cervix and uterus is an accepted clinical practice.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: V or Over-The Counter Use: ___ (Per 21 CFR 801.109)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063382