K040704

JUN 18 2004

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

March 15, 2004

1. General Provisions

Common/Usual Name: Remote Controlled Radionuclide Applicator System

Proprietary Name: Modified Henschke HDR Cervix Applicator
Hilaris/Nori HDR Cervix Applicator

Applicant Name and Address:

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

2. Name of Predicate Devices:

(1)

Model and Manufacturer	K Number
Henschke Applicator; Mick Radio-Nuclear Instruments, Inc.	K871217
Hilaris/Nori Applicator; Mick Radio-Nuclear Instruments, Inc.	K891377
Cervix Applicator; Varian Medical Systems, Inc.	K033371

[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).

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 Mick Radio-Nuclear Instruments, Inc. HDR compatible Tandem and Ovoid Applicators are intended for use in HDR Brachytherapy as described for the predicate device (Cervix Applicator, Varian Medical Systems, K033371). The design of these systems is the similar to that of the predicate devices listed below.

Predicate Device	Manufacturer	K Number
Henschke Applicator	Mick Radio-Nuclear Instruments, Inc.	K871217
Hilaris/Nori Applicator	Mick Radio-Nuclear Instruments, Inc.	K891377

The delivery of radiation therapy to cervix via high dose rate Brachytherapy requires the ability to properly link the applicator to the HDR unit so that the radioactive source can be remotely positioned in the applicator along with the ability to properly localize the sealed sources at the treatment volume providing precise dosimetry and then a stable delivery system from which treatment can be administered. The Mick Radio-Nuclear HDR compatible Tandem and Ovoid Applicators are designed to act as such a device and utilize the same design as previously cleared for other applicators manufactured by Mick Radio-Nuclear Instruments (Vaginal Applicator Set, Shielded, K001544, HDR Tandem/Ring Applicator with Rectal Retractor, K011657).

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

JUN 1 8 2004

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

Re: K040704
Trade/Device Name: HDR Compatible Tandem and Ovoid Applicators
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: March 15, 2004
Received: March 22, 2004

Dear Mr. Mick:

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 such 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

Indications for Use

510(k) Number: ~~To be assigned~~ K040704

Device Name: HDR Compatible Tandem and Ovoid Applicators

Indications for Use:

The applicators presented in this 510(k) notification have been developed to function as Applicators for the positioning of HDR Remote After-Loader sealed sources in the intracavitary treatment of cancer of the vagina and cervix.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Clayman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040704