K011657

AUG 2 7 2001

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

May 25, 2001

1. General Provisions

Common/Usual Name: Remote Controlled Radionuclide Applicator System

Proprietary Name: HDR Tandem/Ring Applicator with Rectal Retractor

Applicant Name and Address:

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

2. Name of Predicate Devices:

(1)

Manufacturer	K Number
Nucletron Corporation Ring Applicator - Complete Set	K953946

[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 Tandem/Ring Applicator with Rectal Retractor is intended for use in Brachytherapy. The delivery of intra-cavitary radiation therapy requires not only proper visualization and localization of the applicator within the treatment volume, but precise dosimetry and a stable delivery system from which treatment can be administered. The Mick Radio-Nuclear HDR Tandem/Ring Applicator with Rectal Retractor meets these requirements.

6. Biocompatibility

No new issues of biocompataibility 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

AUG 2 7 2001

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

Re: K011657
HDR Tandem/Ring Applicator with rectal retractor
(Brachytherapy Applicator)
Dated: May 25, 2001
Received: May 29, 2001
Regulatory Class: II
21 CFR 892.5700/Procode: 90 JAQ

Dear Mr. Mick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 this 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, 4,xxx, 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" (21 CFR 807.97). 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* K011657

Device Name: HDR Tandem/Ring Applicator with Rectal Retractor

Indications for Use:

The use of sealed Radioisotopes to treat tumors within the body has been documented and published since the turn of the century. Modern era Radiation Therapy has developed delivery systems using isotopes of Cesium, Iridium, Iodine, and Gold to name a few examples. Many tumors now are treated by internal exposure to radiation emitted from sealed radioactive sources. Two common modalities for this are Low Dose Rate and High Dose Rate remote afterloading (Brachytherapy). One common application of Brachytherapy is in the treatment of cancer of the cervix. This applicator is designed as an accessory to the Varisource System (Varian Associates K952913) and the Gammamed System (K891131/A) which uses a single radioactive source of Iridium-192 to treat cancer in a wide range of body sites. The HDR Tandem/Ring Applicator with Rectal Retractor is placed in the vicinity of the cervix via the vagina just as described for the predicate device (Nucletron Ring Applicator, K953946) and with a rectal retractor and varying intrauterine tube length diameters, clinical needs can be best optimized along with minimization of dose to the rectum.

Nancy C Brogdon

(Division Sign-Off)
Division of [redacted]
and Radiological Devices
510(k) Number K011657

Concurrence of CDRH, Office of Device Evaluation (ODE)

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