Mick Radio-Nuclear Instruments, Inc.
James Hurlman
Director QA/RA
521 Homestead Avenue
Mount Vernon, New York 10550

March 20, 2020

Re: K200221
Trade/Device Name: CT/MR 2/3 Channel Endometrial, CT/MR Segmented Vaginal, CT/MR Miami, CT/MR Fletcher, CT/MR Henschke FSD, CT/MR Split Ring Applicator Sets, CT/MR Ring & Tandem, including Vienna Accessory Kit
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: Class II
Product Code: JAQ, IWJ

Dear James Hurlman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 28, 2020. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Thalia Mills, OHT7: Office of In Vitro Diagnostics and Radiological Health, 301-796-6641, Thalia.Mills@fda.hhs.gov.

Sincerely,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Mick Radio-Nuclear Instruments, Inc.
% Mr. James Hurlman
Director QA/RA
521 Homestead Avenue
MOUNT VERNON NY 10550

February 28, 2020

Re: K200221
Trade/Device Name: 2/3 Endometrial Applicator Sets, Segmented Vaginal Applicator, HDR Miami Applicator, HDR Compatible Tandem and Ovoid Applicators, CT Compatible F/S/D Applicators, HDR CT Compatible Split Ring Applicator, and CT HDR Tandem Ring Applicator with Rectal Retractor
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: Class II
Product Code: JAQ, IWJ
Dated: January 22, 2020
Received: January 29, 2020

Dear Mr. Hurlman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K200221

Device Name
2/3 Endometrial Applicator Sets, Segmented Vaginal Applicator, HDR Miami Applicator, HDR Compatible Tandem and Ovoid Applicators, CT Compatible F/S/D Applicators, HDR CT Compatible Split Ring Applicator, and CT HDR Tandem Ring Applicator with Rectal Retractor

Indications for Use *(Describe)*
2/3 Endometrial Applicator Sets: A manual radionuclide applicator system, a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy.

Segmented Vaginal Applicator: The use of sealed Radioisotopes to treat tumors within the body has been documented and published since the turn of the century. Modem era Radiation Therapy has developed delivery systems using isotopes of Cesium, Iridium, Iodine, and Gold to name a few examples. Many tumors are now treated by internal exposure to radiation emitted from sealed radioactive sources.
Two common modalities of this are Low Dose Rate and High Dose Rate remote afterloading (Brachytherapy). One common use of Brachytherapy is in the treatment of cancer of the vaginal process. The system described in this 510(k) has been developed to function as an applicator for the positioning of sealed sources in the intracavitary treatment of the vagina.

HDR Miami Applicator: 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 lridium-192 to treat cancer in a wide range of body sites. The Miami Applicator is placed in the vicinity of the cervix via the vagina just as described for the predicate device (Nucletron Miami Vaginal Applicator, K953946) and different diameter sleeves and intrauterine tubes, can be optimized to best meet the clinical needs of the patient along with minimization of dose to the mucosa.

HDR Compatible Tandem and Ovoid Applicators: 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 intra-cavitary treatment of cancer of the vagina and cervix.

CT Compatible F/S/D Applicators: CT Compatible F/S/D 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.

HDR CT Compatible Split Ring Applicator: 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.

CCT HDR Tandem Ring Applicator with Rectal Retractor: The Mick Radio-Nuclear Instruments, Inc. CT HDR Tandem/ Ring Applicator with Rectal Retractor is indicated for High Dose Rate irradiation of the uterus and cervix.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Special 510(k) Summary for compliance with CFR 807.92

March 3, 2020

1. General Provisions

Common Name: Radionuclide brachytherapy source (JAQ) and Manual radionuclide applicator system (IWJ).

Proprietary Name: The GYN 1 Applicator Family - Intracavitary

- CT/MR Fletcher,
- CT/MR Henschke FSD,
- CT/MR Split Ring Applicator Sets

The GYN II Applicator Family

- CT/MR Segmented Vaginal,
- CT/MR Miami,
- CT/MR 2/3 Channel Endometrial,
- CT/MR Ring & Tandem, including Vienna Accessory Kit

Owner Name	Mick Radio-Nuclear Instruments, Inc.
Address	521 Homestead Avenue Mount Vernon, New York 10550
Telephone	(914) 667-3999
Fax	(914) 665-8834
Contact Name	Isaac Strickland
Contact email	isaac.strickland@micknuclear.com

2. Name of Predicate Device:

Original 510(k) #	Trade/ Device Name	Regulation Number	Regulatory Classification	Product Code	Review Panel
K993472	Segmented Vaginal Applicator	21 CFR 892.5700	Class II	JAQ	Radiology
K020176	HDR Miami Applicator HDR Brachytherapy Applicator	21 CFR 892.5700	Class II	JAQ	Radiology
K040704	HDR Compatible Tandem and Ovoid Applicators (Henschke)	21 CFR 892.5700	Class II	JAQ	Radiology
K063381	CT F/S/D Compatible Applicators	21 CFR 892.5700	Class II	JAQ	Radiology
K063382	HDR CT Compatible Split Ring Applicator	21 CFR 892.5700	Class II	JAQ	Radiology
K122840	CT HDR Tandem/Ring Applicator with Rectal Retractor	21 CFR 892.5700	Class II	JAQ	Radiology
K871216	2/3 Endometrial Applicator Sets	21 CFR 892.5650	Class I	IWJ	Radiology

3. Reason for this Special 510(k) Premarket Notification

The purpose for this bundled submission is the modification of the labeling and Instructions for Use for each of the listed devices to add MR Conditional labeling to each of them.

4. Classification

This devices are classified as listed in the table above.

5. Intended Use and Device Description

2/3 Channel Endometrial Applicator Sets: The 2/3 Channel Endometrial Applicator is designed for the treatment of the endometrium and cervix. The applicator set includes 3 intrauterine tubes that are available in 3 cm and 5 cm configurations. These intrauterine tubes can be assembled using only 2 or all 3 intrauterine tubes, depending on the patient requirements. The only change to the device will be the labeling that the device is now MR Conditional.

Henschke Applicator Set: The Henschke Applicator is based on "Henschke style" geometry for brachytherapy of the endometrium and cervix. This applicator is similar in design to the Fletcher Applicator with the exception of semispherical ovoids. These ovoids are ideal for patients with narrow vaginas due to their small size, the ovoid tube is closer to the surface on the side of the cervix while maintaining distance within the fornices. The tandem is inserted into the endometrium at a pre-determined depth and secured in place with the cervical stop. The only change to the device will be the labeling that the device is now MR Conditional.

Fletcher (FSD) Applicator Set: The Fletcher Applicators are based on "Fletcher style" geometry for brachytherapy of the endometrium and cervix. The ovoids are cylindrical to create equal spacing in the vaginal fornices for a symmetrical dose distribution in this area. The tandem is inserted to into the endometrium at a pre-determined depth and secured in place with the cervical stop. The only change to the device will be the labeling that the device is now MR Conditional.

5. Intended Use and Device Description con't.:

Miami Applicator Set: The Miami Applicator is designed for treatment of the vagina and cervix and includes an intrauterine tube for the treatment of the endometrium, as required. The design incorporates 7 treatment channels around the periphery of the cylinder body and includes a center channel that can accommodate an intrauterine tube. The intrauterine tubes are available with either a 30° angled tip or in a straight (0° angle) configuration. A stump plug is provided to seal the end of the applicator when an intrauterine tube is not required. Build-up caps are available for the cylinder body to provide added spacing between the mucosa and radioactive source. This applicator provides additional treatment options, with the peripheral channels, to increase the dose to the target area while limiting the dose to normal tissue. The only change to the device will be the labeling that the device is now MR Conditional.

Ring & Tandem Applicator Sets: The Ring & Tandem Applicator is based on the Stockholm technique for brachytherapy of the endometrium and cervix. The applicator consists of a ring tube and intrauterine tube that, when combined, create a fixed geometry and form a 90° angle. Build up caps of different diameters are provided for the ring tube that provide additional spacing between the radioactive source and mucosa. Including the Vienna Ring and Tandem Accessory Kit. The only change to the device will be the labeling that the device is now MR Conditional.

Segmented Vaginal Applicator Set: The Segmented Vaginal Applicator is designed for treatment of the vagina and cervix and includes an intrauterine tube for the treatment of the endometrium, as required. The intrauterine tubes are available in different angles and lengths to meet anatomical requirements. The four individual segment design allows the applicator length to be adjustable based on the treatment volume. Additionally, the segments are available in different diameters to match the patient's anatomy. The only change to the device will be the labeling that the device is now MR Conditional.

Split Ring Applicator Sets: The Split Ring Applicator's patented design combines the benefits of several other intracavitary applicators. The ring tubes can be configured as a closed/complete ring or separated/" split" into four different distances, symmetrically or asymmetrically with the spacing bracket. Build-up caps of different diameters fit over the ring tubes to provide additional tissue spacing distance between the radioactive source and the cervix. The only change to the device will be the labeling that the device is now MR Conditional.

Vienna System: The Mick Radio-Nuclear Instruments, Inc. Vienna System is intended to be used as an accessory to the Mick CT HDR Tandem I Ring Applicator and is indicated for High Dose Rate irradiation of the uterus and cervix. The Vienna System consists of perforated Build-Up Caps and complementary Needle Collectors which connect to the Mick CT HDR Tandem Ring Applicator. Pre-bent interstitial needles are intended to be used with the Vienna System but they

are not manufactured by Mick Radio-Nuclear Instruments, Inc. and are not part of this submission.

Build-Up Caps
When used with the CT HDR Tandem/Ring Applicator, the Vienna Build-Up Caps enable the introduction of up to nine (9) interstitial needles around the circumference of the ring to enhance the standard HDR treatment. The Vienna System is not designed to be used with any Rectal Retractor due to the introduction of the interstitial needles.

Needle Collectors
When used in conjunction with the Vienna Build-Up Caps, the Needle Collectors will maintain and control the positioning of an array of up to nine (9) interstitial needles. The Needle Collectors are part of the Vienna System and as such, are not designed to be used with any

Rectal Retractor.
The Vienna System is designed to be used as an accessory with the Applicator and this does not alter the indications for use and is MR Conditional.

6. Drawings

Drawings of the devices are in the Device Description section of this submission.

7. Manufacturing Process

This device is manufactured according to Good Manufacturing Practices (GMPs) as defined in 21CFR part 820. The processes used to fabricate these devices are identical to those used for the predicate device described in this 510(k) notification.

8. Biocompatibility

No new issues of biocompatibility are raised with regard to the modification of the devices for MR Conditional labeling.

9. Summary of Substantial Equivalence

There have been no changes to the devices or their intended use.
Performance Test Results

In vitro Testing
Not applicable to the modification for the device. By introducing this device, no new issues of safety or effectiveness are raised.

In vivo Testing
Not applicable for the modification for the device.

Functional Testing
Computational Modeling of Mick Radio-Nuclear Instruments HDR Brachytherapy Intracavitary Applicators for Radiofrequency-Induced Heating Evaluation Final Report. Results = MR Conditional.

10. Summary of Similarities and Differences

These devices are identical in design, manufacture, construction and materials and have the same intended use and performance characteristics to their original 510(k)'s. The modification to the devices will be to put MR Conditional labeling on both the individual product labeling and the IFU's. The fundamental scientific technology is unchanged from the original predicate device.

11. Comparison Table

The Table below compares the modification of these devices to the predicate device (Original 510(k). Included in these tables are a comparison of the materials and intended uses of these devices.

Original 510(k) #	Trade/ Device Name	Predicate Device (Original 510(k))	Modified Device
K993472	Segmented Vaginal Applicator	Materials – MR Conditional	Same
		MR Testing – Not Complete	MR Testing – Complete
		MR Conditional Labeling - No	MR Conditional Labeling - Yes
		Intended Use	Same
K020176	HDR Miami Applicator HDR Brachytherapy Applicator	Materials – MR Conditional	Same
		MR Testing – Not Complete	MR Testing – Complete
		MR Conditional Labeling - No	MR Conditional Labeling - Yes
		Intended Use	Same
K040704	HDR Compatible Tandem and Ovoid Applicators (Henschke)	Materials – MR Conditional	Same
		MR Testing – Not Complete	MR Testing – Complete
		MR Conditional Labeling - No	MR Conditional Labeling - Yes
		Intended Use	Same
K063381	CT F/S/D Compatible Applicators	Materials – MR Conditional	Same
		MR Testing – Not Complete	MR Testing – Complete
		MR Conditional Labeling - No	MR Conditional Labeling - Yes
		Intended Use	Same
K063382	HDR CT Compatible Split Ring Applicator	Materials – MR Conditional	Same
		MR Testing – Not Complete	MR Testing – Complete
		MR Conditional Labeling - No	MR Conditional Labeling - Yes
		Intended Use	Same
K122840	CT HDR Tandem/Ring Applicator with Rectal Retractor	Materials – MR Conditional	Same
		MR Testing – Not Complete	MR Testing – Complete
		MR Conditional Labeling - No	MR Conditional Labeling - Yes
		Intended Use	Same
K871216	2/3 Endometrial Applicator Sets	Materials – MR Conditional	Same
		MR Testing – Not Complete	MR Testing – Complete
		MR Conditional Labeling - No	MR Conditional Labeling - Yes
		Intended Use	Same