DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mick Radio-Nuclear Instruments, Inc.
% Mr. Chuck Smith
Manager, Quality Assurance
521 Homestead Avenue
MOUNT VERNON NY 10550

May 31, 2016

Re: K150979
Trade/Device Name: CT/MR M.A.C. Interstitial GYN Template
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: April 26, 2016
Received: April 27, 2016

Dear Mr. Smith:

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K150979

Device Name
CT/MR M.A.C. Interstitial GYN Template

Indications for Use *(Describe)*
The CT/MR M.A.C Interstitial GYN Template is indicated for high dose rate irradiation of vaginal, cervical, endometrial and urethral cancers. It is intended to provide a needle guidance system for the introduction of needles and a vaginal obturator into the treatment site.

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.

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Traditional 510(k) Summary for compliance with CFR 807.92

April 19, 2016

K150979

1. General Provisions

Common Name:	CT/MR M.A.C. Interstitial GYN Template
Proprietary Name:	CT/MR M.A.C. Interstitial GYN Template
Owner Name:	Mick Radio-Nuclear Instruments, Inc. (MRNI)
Address:	521 Homestead Avenue Mount Vernon, New York 10550
Telephone:	(914) 667-3999
Fax:	(914) 665-8834
Contact Name:	Chuck Smith
Contact email:	chuck.smith@bebig.com

2. Reason for this Traditional 510(k) Premarket Notification

The purpose of this Traditional 510(k) submission is to obtain clearance to market the CT/MR M.A.C. Interstitial GYN Template.

3. Classification

This device is classified as a Class II device according to 21 CFR 892.5700. The device classification name is a "Remote Controlled Radio-nuclide Applicator System" and the corresponding product code is JAQ.

4. Intended Use

The CT/MR M.A.C. Interstitial GYN Template is indicated for high dose rate irradiation of vaginal, cervical, endometrial and urethral cancers. The device is intended to provide a needle guidance system for the introduction of needles and a vaginal obturator into the treatment site.

5. Device Description

The CT/MR M.A.C. GYN Interstitial Template Set includes a labeled template, a slotted channel Vaginal Obturator, a set of intrauterine tubes in different angles, locking collets to accommodate both peripheral needle channels in the Template and needle channels in the central Vaginal Obturator, an Allen wrench to lock the intrauterine tube in the Obturator and a collet wrench to securely affix the needles by way of individual collets to both the Template and the vaginal obturator. The set features an Obturator – Template design with an optional intrauterine tube enabling complete or targeted treatment of the vagina, cervix, endometrium and parmetrium.

The Set is available in different gauge sizes to accommodate various needles. The associated Template, Obturator and collets are provided in the specified gauge size for use with the specific size needle indicated.

The Template is made of PPSU and medical grade Titanium. It is shaped optimally to conform to the patient's perineum to provide a more comfortable fit and to ensure better needle placement. The Template set includes a 14cm long central Vaginal Obturator (which is produced from Delrin) with a matrix of 6 needle channels positioned around the periphery of the Vaginal Obturator for individual needle placement. There is a 19cm long Vaginal Obturator as an available option. Both Obturators are 2.5cm in diameter. All Obturator Needles are secured with individual Locking Obturator Needle Collets

There is a peripheral matrix of needle channels that are positioned at 2 cm and 3 cm from the central axis around the Vaginal Obturator to further broaden the dose distribution, according to the treatment plan. Each Peripheral Needle is affixed individually by using the Peripheral Needle Collets. The collets used for the Vaginal Obturator and for the peripheral access needle channels have different threads but the same Collet Wrench is used by both to lock the respective collets in place for ease of use.

The components in the CT/MR M.A.C. Interstitial GYN Template are CT compatible and MR Conditional. This is achieved by using Titanium and plastic components that are inserted into the patient. This includes the Vaginal Obturator and the 3 tandems included in the set.

6. Name of Predicate Devices:

The device included in this submission is substantially equivalent to the legally marketed predicate devices cited in the following Table 1.

There is a Primary predicate and a Secondary predicate identified.

Primary (manufactured by Mick Radio-Nuclear Instruments, Inc.)

- HDR Miami Applicator

Secondary

- HDR Contour TP Template and Implant Accessories (manufactured by Mick Radio-Nuclear Instruments, Inc.)

Table 1

Device	Type of Predicate	Predicate Component	Manufacturer	K Number
HDR Miami Applicator	Primary	Vaginal Obturator	Mick Radio-Nuclear Instruments, Inc.	K020176
HDR Contour TP Template and Implant Accessories	Secondary	Template Body	Mick Radio-Nuclear Instruments, Inc.	K993400
AOS Interstitial Templates, Needles &	Reference Device	Template System	Alpha-Omega Services	K062823

Accessories				

7. Predicate Device Rationale and Substantial Equivalence Discussion

PRIMARY PREDICATE

CT/MR M.A.C. Interstitial GYN Template is designed to take advantage of two separate device technologies manufactured by Mick Radio-Nuclear Instruments, Inc. It takes the intracavitary features of the HDR Miami Applicator and combines this with a grid pattern for interstitial needle placement, similar to the HDR Contour TP Template. The grid pattern is shaped in a circular pattern around a central obturator enabling complete or targeted treatment of the vagina, cervix, endometrium and parmetrium. Like the Miami Applicator, the CT/MR M.A.C. Interstitial GYN Template features a central obturator for intracavitary needle guidance as well as additional needle channels around the periphery. The Obturator contains the features of the HDR Miami Applicator, combined with a template or grid design. This provides a very flexible device, allowing a wide variety of needle placement, both in the Template field and through the use of the vaginal obturator. The design and manufacturing process for the CT/MR M.A.C. Interstitial GYN Template is identical to both primary predicate devices and share similar materials.

The HDR Miami Applicator has been marketed since 2002 as a GYN treatment device and the CT/MR M.A.C. Interstitial Template shares many of the same features, notably the use of the vaginal obturator and intrauterine tubes. In the Miami Applicator, the obturator is utilized to introduce an HDR source directly into the obturator and the CT/MR M.A.C. Interstitial Template uses an obturator of the same design to introduce the HDR source through flexible or rigid needles or through an intrauterine tube, identical to the Miami Applicator. The utilization of an intrauterine tube allows for flexible and widespread treatment of the cervix and endometrium. The needle grid of the CT/MR M.A.C. Interstitial Template has a central opening that allows the passage and placement of the vaginal obturator into the treatment site. The obturator is positively affixed by the use of a locking knob which allows for a very secure placement to the desired treatment depth.

SECONDARY PREDICATE

The HDR Contour Template is a needle guidance device intended for Prostate Brachytherapy and has been marketed and used since 1999. The template design is shaped to comfortably fit against the perineum and is also compatible to several ultrasound stepping units. The CT/MR M.A.C. Interstitial GYN Template shares these features. The CT/MR M.A.C. Interstitial Template needle grid is based on the proven principles of the HDR Contour Template while conforming to the GYN treatment site. The needle grid pattern is shaped to allow needle placement in the target treatment area, throughout the entire vagina. Mick Radio-Nuclear Instruments, Inc. utilizes the same template manufacturing process and expertise in manufacturing templates to very exacting standards of operation and this experience and knowledge is used to produce the CT/MR M.A.C. Interstitial GYN Template to the same high standards and tight tolerances required of needle placement templates.

The Alpha Omega Interstitial Templates, Needles and Accessories were chosen as a reference device based on a similar intended use and the ability to provide a fixed array of needles and a vaginal guide into the treatment site. This device shares the same

treatment modality as the CT/MR M.A.C. Interstitial Template, however there are significant differences. The vaginal guide (or obturator) is affixed by the use of an O-Ring which is not used in the CT/MR M.A.C. Interstitial Template. Also the materials used in the Alpha Omega device are made from silicone and the manufacturing process are not the same. The Alpha Omega device also is provided sterile is single use and the CT/MR M.A.C. Interstitial Template is not provided sterile but is reusable.

8. Summary of Similarities and Differences

The similarities between the CT/MR MAC Interstitial GYN Template and the HDR Miami Applicator is the use of the same material and design in the vaginal obturators. The indications for use are the same in both applicators. The same principles and design have been used for the obturator in the CT/MR MAC Interstitial GYN Template.

The same technology is used for aligning the needles along the periphery of the obturator (6 individual channels to a prescribed depth) and the same technology and design is used for the introduction into and the locking of the central intrauterine tubes onto the obturator. There are similar lock knobs used to positively affix the intrauterine tube to the desired depth of penetration through the cervix and into the uterus for treatment. Both applicators are reusable.

The Template Body of the CT/MR MAC Interstitial GYN Template shares the same design as the HDR Contour Template; however, the needle channel pattern is different in order to suit the anatomy. The shape of the templates are similar in order to fit the perineum and the needles in both templates can be positively locked in place using individual collets to ensure the safe and effective treatment. Needle sizes are variable to accommodate various treatment plans. Both applicators are reusable.

The operating principles are the same in the predicates named. All of the devices are used to introduce an HDR source into the treatment site through a central obturator, an intrauterine tube or a hollow needle. There is no electrical energy used in the operation of the devices

9. Manufacturing Process

This device is manufactured according to Good Manufacturing Practices (GMPs) as defined in 21CFR part 820. The processes used to fabricate the CT/MR MAC Interstitial GYN Template is very similar to the two Mick Radio-Nuclear Instruments devices identified as primary predicate devices described in this 510(k) notification.

10. Biocompatibility

No new issues of biocompatibility are raised with regard to the introduction of the CT/MR MAC Interstitial GYN Template. Medical grade materials are used in the manufacture of this device.

However, biocompatibility testing has been performed on an applicator made from the same materials as the CT/MR MAC Interstitial GYN Template and considered a worst case scenario from device construction.

11. Non Clinical Testing

To operate in CT and MR environments, the CT/MR M.A.C. Interstitial GYN Template has been tested in a non-clinical environment, both for CT compatibility and for MR compatibility. CT compatibility testing has been performed and the results of the testing reveal very little artifacts and clinicians have certified that the CT images are not negatively impacted by artifacts due to the presence of the CT/MR M.A.C. Interstitial GYN Template and are of sufficient quality for use in the radiation therapy clinical workflow.

In order to operate in the MR environment, testing has been performed using both 1.5T and 3.0T scanners to validate the fact the due to the materials used and the geometry of the device there are favorable results achieved in the testing. The tests performed measured the displacement, torque, artifact results and heating results.

The calculated displacement force corresponded to an assumed displacement of 1 degree and the calculated force in all cases was less than that associated with gravity, in accordance with the relevant standard. No torque effect was observed on the CT/MR M.A.C. Interstitial GYN Template with associated devices at approximate isocenter of the 3.0T magnet when the device was caused to rotate through three complete revolutions.

For image artifacts, the maximal extent of artifact associated with portions of the device expected to be within the body of the patient was 4.8cm on a 3.0T gradient-echo image. Observed artifacts were consistent with expectations due to the metallic construction.

Heating testing was performed using both the 1.5T and 3.0T scanners and the results of the testing indicate that with the application of a limitation to the Normal Operating Mode at a SAR of 1.0W/kg, the largest expected total temperature rise at the limiting field strength, with 15 minutes of scanning is less than 6°C. This level of heating is not expected to cause adverse effects. All comprehensive test data and results are on file.

12. Comparison Table

The Table below compares the CT/MR MAC Interstitial GYN Template to the predicate devices.

K Number / Owner	K993400 / Mick Radio-Nuclear Instruments, Inc.	K020176 / Mick Radio-Nuclear Instruments, Inc.	TBD / Mick Radio-Nuclear Instruments, Inc.
Device Name	HDR Contour TP Template & Implant Accessories	HDR Miami Applicator	CT/MR M.A.C. Interstitial GYN Template
Intended Use	Providing a means of visualizing and localizing the placement of needles used in radiotherapy of the prostate.	For use in Brachytherapy in delivering intra-cavitary radiation.	Provide a needle guidance system for the delivery of high dose rate irradiation of vaginal, cervical, endometrial and urethral cancers.
Obturator Material	N/A	Delrin (USP Class VI)	Delrin (USP Class VI)
Template Body Material	PPSU	N/A	PPSU
Template Lock Plate Insert Material	Titanium	N/A	Titanium
Collets	Titanium	N/A	Titanium
Intrauterine Tandems	N/A	Titanium	Titanium
Method for affixing Obturator	N/A	Locking Knob	Locking Knob
Method for affixing Needles	Lock Plate or optional Locking Collets	N/A – No provisions for needles	Individual Locking Collets
Device Provided Sterile	No	No	No
Single Use	No	No	No
Reusable	Yes	Yes	Yes