Mick Radio-Nuclear Instruments, Inc.
℅ James Hurlman
Director, Quality Management & Regulatory Affairs
521 Homestead Avenue
MOUNT VERNON NY 10550

August 30, 2023

Re: K230155
Trade/Device Name: Mick Valencia Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: Class II
Product Code: JAQ
Dated: August 2, 2023
Received: August 3, 2023

Dear James 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230155

Device Name
MICK Valencia Applicator Sets

Indications for Use *(Describe)*

The intended use of the MICK Valencia Applicator is to facilitate the placement of a radioactive source near the target area on intact skin for remote afterloading brachytherapy treatment.

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.

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Mick Radio-Nuclear Instruments, Inc.
A BEBIG Medical Company

521 Homestead Ave
Mount Vernon, NY 10550
USA
www.micknuclear.com

Main: +1 914 667 3999
Fax: +1 914 665 8834
Toll Free: +1 877 597 MRNI
E-Mail: isaac.strickland@micknuclear.com

Traditional 510(k) Summary of Safety and Effectiveness Information As required by section 807.92(c)

K230155

August 28, 2023

1. General Provisions

Common Name: Remote controlled radionuclide brachytherapy source (JAQ)

Proprietary Name: Mick Valencia Applicator Set

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
K073107	Valencia Skin Applicator Set	21 CFR 892.5700	Class II	JAQ	Radiology

3. Classification

Class 2,
Product Code: JAQ
Regulation Number: 21 CFR 892.5700

4. Intended Use

The intended use of the Mick Valencia Applicator is to facilitate the placement of a radioactive source near the target area on intact skin for remote afterloading brachytherapy treatment.

5. Device Description

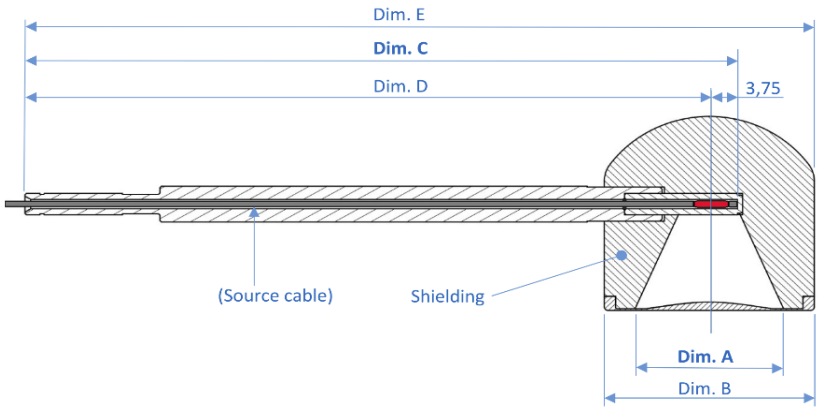
The Mick Valencia Applicator is used for remote afterloading treatment on intact skin/surface. The applicator with associated plastic cap is placed onto the patient, locked into position, and connected to the remote afterloading equipment (via transfer tube) to facilitate the brachytherapy treatment in accordance with the physician approved treatment parameters. The radioactive source travels from the machine into the applicator and deliver the desired dose distribution to the defined treatment volume. When the treatment is completed, the source returns to the machine. The applicator is disconnected from the treatment unit and removed from the patient.

The applicator does not control the treatment unit, it strictly provides a treatment path for the radioactive source. The Mick Valencia applicator is temporarily placed during the treatments designed as a closed system to prevent the radioactive source from coming in contact with bodily fluids.

The device is the same as the legally marketed device cited, both in design and materials.

MICK Valencia Skin Applicator

Elekta Valencia Skin Applicator



MICK Valencia Skin Applicator

Set	Model	Description	Dim A	Dim B	Dim C	Dim D	Dim E
1503 (BEBIG)	1503-20	Valencia applicator 20mm	20	28	95	91.25	105
	1503-30	Valencia applicator 30mm	30	36	115	111.25	129
1504 (Varian)	1504-20	Valencia applicator 20mm	20	28	113	109.25	123
	1504-30	Valencia applicator 30mm	30	36	113	109.25	127

6. 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.

7. Non-Clinical Tests

Non-clinical testing is performed on the Mick Valencia Applicator connection to the transfer tube (the transfer tubes are supplied by the Afterloader manufacturer). These are bench top tests, performed on every applicator produced.

8. Afterloader Compatibility

The Mick Valencia Applicator Set is compatible with the following HDR afterloaders, BEBIG Medical GmbH model Saginova®, Varian model GammaMedplus™ and Varian model Bravos afterloaders. The Mick Valencia Applicator sets are not compatible with Elekta afterloaders.

9. Biocompatibility

The materials in the subject device are the same as the previously cleared predicate device and thus, there are no new biocompatibility concerns.

10. Summary of Similarities and Differences

The Mick Valencia Applicator Sets are substantially equivalent in design, manufacture, construction and materials and have the same intended use and performance characteristics to the predicate device. The fundamental scientific technology is unchanged from the original predicate device. The connectors used on the Mick Valencia Applicator sets, to attach to the afterloaders transfer tubes, are substantially equivalent to the predicate device in their fundamental design for a standard click fit type connector.
Some differences from the predicate device are as follows;

1) Our device has more of a dome shape then the predicate device,

2) the shaft and tube diameters are slightly thicker, and
3) the Mick Valencia Applicator set comes with two marker caps; one of the marker caps is used for applicator placement, while the other cap is placed on the target area for treatment.
4) The Mick Valencia Applicator set comes in two sizes, in 20 mm & 30 mm diameters and both sizes are compatible with the BEBIG Medical GmbH model Saginova®, the Varian model GammaMedplus™ and the Varian model Bravos afterloaders.

11. Comparison Table

The MICK Valencia Applicator Set has the same functionality, performance and design as the predicate device the Nucletron/Elekta Valencia Skin Applicator. The equivalence is based on a comparison of clinical, technical and biological aspects of the two devices. The following table identifies the clinical, technical and biological aspects of the predicate device and the MICK Valencia Skin Applicator Set:

Equivalence Table	**Predicate Device Nucletron/Elekta Valencia Skin Applicator K073107**	**MICK Valencia Skin Applicator Sets K230155**
Clinical Aspects		
Intended Purpose: HDR Brachytherapy of skin/surface lesions	Yes	Yes
Suitable for any patient with skin/surface lesions (benign or malignant) regardless of their age, gender, ethnicity or predisposition.	Yes	Yes
Can be used for any site on the body surface that has been prescribed HDR Brachytherapy treatment	Yes	Yes
Applicator is placed in direct contact with the treatment area/skin surface.	Yes	Yes
Long term side effects are limited to a slight mark or discoloration of the skin and/or hair loss in the treatment area and is dependent on the prescription dose	Yes	Yes
Patient is under the care of a Radiation Oncologist, physicists, dosimetrists and radiation therapists trained in Radiation Oncology and, specifically, brachytherapy techniques	Yes	Yes
Technical Aspects		
Available in 20 mm and 30mm diameter	Yes	Yes
Only one source position is used for the treatment	Yes	Yes
Source delivery through a single channel (transfer	Yes	Yes

tube)		
Tungsten shielded applicator with reinforced shielding in the dome to reduce dose from the backside of the applicator	Yes	Yes
Includes flattening filter for homogeneous dose distribution	Yes	Yes
Plastic caps available: providing a flat surface improved homogeneous dose	Yes	Yes
Filtering low dose scatter radiation	Yes	Yes
Improved applicator positioning by imprinting skin surface	Yes	Yes
2 types of caps available (with and without a marker)	Yes	Yes
The device is reusable	Yes	Yes
The applicator can be cleaned and disinfected	Yes	Yes
Applicator is MR unsafe	Yes	Yes
Provides and unobstructed path for the radioactive source	Yes	Yes
Connects securely to remote afterloading brachytherapy equipment via transfer tubes	Yes	Yes
Biological Aspects		
The applicators are made from the same materials. (tungsten, plastic caps, stainless steel)	Yes	Yes
The applicators have the same manufacturing process	Yes	Yes
The applicators come in direct contact with skin surface	Yes	Yes
Caps are provided for treatment to provide filtration of scatter radiation.	Yes	Yes
The applicators are made from materials that are biocompatible	Yes	Yes
Provided Non-Sterile	Yes	Yes

12. Summary of technological considerations:

The Mick Valencia Applicator Set is substantially equivalent to the cleared predicate device Valencia Skin Applicator Set, 510(k): K073107