Best Medical International, Inc.
% Manny Subramanian, Ph.D.
Director, Research & Development
7643 Fullerton Road
SPRINGFIELD VA 22153

April 13, 2018

Re: K162499
Trade/Device Name: Best Instruminal Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: March 9, 2018
Received: March 12, 2018

Dear Dr. Subramanian:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K162499

Device Name
Best® Intraluminal Balloon Applicator for Brachytherapy

Indications for Use *(Describe)*
Best® Intraluminal Balloon Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver intraluminal radiation to an existing body lumen such as the esophagus or bronchus. It is supplied as a single-use sterile device. The device is indicated for use under the direct supervision of a qualified physician.

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."

Best Medical International, Inc.
Best Intraluminal Balloon Applicator
510(k) Summary (K162499)

Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the proposed Best Medical International, "Best® Intraluminal Balloon Applicator for Brachytherapy "

1. Manufacturer: Best Medical International, Inc.
7643 Fullerton Road
Springfield, VA 22153
Phone: (703) 451-2378
Fax: (703) 451-4736.

Contact Person: Manny Subramanian, PhD
Director, Research and Development
Phone: (703) 451-2378 Ext 151
Fax: (703) 451-4736.

Original Submission Date: August 30, 2016
Updated Submission Date: April 11, 2018

2. Device Name:

Trade Name: Intraluminal Balloon Applicator for Brachytherapy

Name: "Best® Intraluminal Balloon Applicator for Brachytherapy" K162499

Classification: Remote Controlled Radionuclide Source Applicator
21 CFR 892.5700

Regulatory Class: II

Product Code: JAQ

3. Predicate Device: Varian® Centering Intraluminal Applicator - 510(k) K082653

4. Device Description:

The Best® device is a single catheter brachytherapy device consisting of an inflatable distal spherical balloon for anchoring and/or stabilizing and a series of inflatable balloons for centering the treatment catheter within the lumen. The catheter can be attachment to a commercially

available High Dose Rate remote afterloader for passage of the source wire and radiation source into the catheter lumen. A removable flexible guide cable is positioned in the central treatment catheter for initial placement in the existing body lumen. Proximal ports are also provided with Luer-lock type connectors for inflation of the distal anchoring/stabilizing balloon inflation/deflation and for inflation of the series of centering balloons, either simultaneously or individually.

5. Intended Use:

Best® Intraluminal Balloon Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver radiation to an existing body site such as the esophagus or bronchus. It is supplied as a single-use sterile device. The device is indicated for use under the direct supervision of a qualified physician.

6. Comparison of Technological Characteristics: "Best® Intraluminal Balloon Applicator for Brachytherapy" shares many structural and functional features with the FDA-approved Varian® Centering Intraluminal Applicator. Both are single catheter devices that are intended to deliver radiation to cancerous region within an existing body lumen. They have similar design characteristics, same operating principle and similar technological characteristics. Therefore, it can be concluded that the proposed device is substantially equivalent to the Predicate device.

	The Best ® Device	**Predicate Device**
Device	Best® Intraluminal Balloon Applicator for Brachytherapy K162499	Varian® Intraluminal Applicator Set GM 1000620 – K151022
Design	Treatment Catheter - 6 Fr (2.0 mm) Extruded thermoplastic Guide Tube – 4mm – 10 mm O.D. Length – 70 cm – 150 cm Extruded thermoplastic Guide Wire – 0.9 mm O.D. Length – 80 cm – 160 cm Stainless steel X-ray marker – Tungsten	Treatment Catheter - 5 FR (1.67 mm) Extruded thermoplastic Guide Tube – 3 mm O.D. Length – 90 cm Extruded thermoplastic Guide Wire - 0.9 mm O.D. Length – 260 cm Stainless steel X-ray marker - Tungsten
Packaging	Individual provided sterile	Individual provided sterile
Sterilization Method	Ethylene Oxide	Gamma sterilization
Biocompatible	Fully biocompatible – single use	Fully biocompatible – single use
Anatomical Sites	Intralumenal, esophageal, endo-bronchial	Intralumenal, esophageal, endo-bronchial, bile duct
Where used	Brachytherapy treatment room Physician guidance	Brachytherapy treatment room Physician guidance

7. Non-Clinical Performance Data

Performance tests were conducted to evaluate and characterize the performance of the Best® Intraluminal Balloon Applicator for Brachytherapy. Preclinical tests included dimensional comparisons of the inflation regions at various volumes and HDR source transition into and out of the treatment catheter (see Attachment 9). The Best® Intraluminal Balloon Applicator for Brachytherapy performed as intended. Additionally,

- the device is constructed of materials that are not significantly affected by radiation to which they will be exposed during the lifetime of the product (single use)
- the device may be sterilized effectively
- the device will not be resterilzed

8. Clinical Performance Data

No clinical performance data was collected in support of this premarket notification.

9. Conclusion

The Best® Intraluminal Balloon Applicator for Brachytherapy has the above similarities to the predicated device in that: it has the same intended use; it has similar design characteristics; same operating principle and similar technological characteristics. Therefore, it can be concluded that the proposed device is substantially equivalent to the Predicate device.