Section 5 510(k) Summary

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

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The assigned 510(k) Number: K183332

1. Submitter

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2 **Device Name**

Proprietary Name	"BRAXX" Esophageal Brachytherapy Applicator
Common name	Esophageal Brachytherapy Applicator
Product Code	JAQ
Device	System, Applicator, Radionuclide, Remote-Controlled
CFR Classification	21 CFR 892.5700
Device Class	II
Classification Panel	Remote controlled radionuclide applicator system

3 **Predicate Device Name**

510(k) number:	K142719
Trade or proprietary name:	E-App (Esophageal Applicator)
Manufacturer:	BIONIX RADIATION THERAPY, LLC
510(k) number:	K162499
Trade or proprietary name:	Intraluminal Balloon Applicator for Brachytherapy
Manufacturer:	Best Medical International, Inc

5. **Intended Use:** The Esophageal Brachytherapy Applicator is intended for use with commercially available afterloader during brachytherapy. The purpose of the device is for delivery

of radioactive source to the esophagus. This device is sterile, disposable and single-use.

Special Conditions for Use Statement(s): For prescription use only

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the Esophageal Brachytherapy Applicator is substantially equivalent to the predicate device as summarized in ***Table 1***.

Table 1

Device name	Subject device: Esophageal Brachytherapy Applicator	Predicate device: E-App	Predicate device: Best® Intraluminal Balloon Applicator for Brachytherapy
Intended Use	The Esophageal Brachytherapy Applicator is intended for use with commercially available afterloader during brachytherapy. The purpose of the device is for delivery of radioactive source to the esophagus. This device is sterile, disposable and single-use.	The GC Medtech Esophageal applicator(E-App) is an applicator used to facilitate delivery of a prescription of radiation to the esophagus when used in conjunction with a high dose rate after-loader.	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.
Target patient Population	Esophageal cancer patients	Same	Same
Target User Population	Radiation oncologists	Same	Same
Anatomical Site	Esophagus	Same	Same
Where Used	Hospital O.R. room	Same	Same
Design	A main catheter with inflatable balloons	Same	Same
Performance	For centering the treatment catheter (radioactive source) within the lumen by inflated balloons.	Same	Same
Biocompatible	Fully biocompatible	Same	Same
Sterilization Method	Ethylene Oxide	Same	Same
Single Use	Single use	Same	Same

7. Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the device.

Biocompatibility testing

The biocompatibility evaluation and testing of the Esophageal Brachytherapy Applicator was conducted in accordance with the following standards and guidance, as recognized by the FDA:

- FDA Draft Guidance - Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing", dated 04-23-2013
- ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
- ISO 10993-11, Biological evaluation of medical devices- Part 11: Tests for systemic toxicity.
- USP 151, Pyrogen Test in White Rabbits

Sterilization Validation

Sterilization validation was conducted in accordance with ISO 11135:2014 “Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices”. Sterilization has been validated to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

Mechanical testing

Esophageal Brachytherapy Applicator’s mechanical function and structure integrity were tested and demonstrated that the design specification from design input are fulfilled and that the device raises no safety concern.

8. Conclusion

Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the Esophageal Brachytherapy Applicator is substantially equivalent to the predicate device and raises no new questions of safety or effectiveness.