BRAXX Biotech Co. Ltd
℅ Anita Chen
Consultant
ZhengCheng Consulting Limited Company
6F., No.148, Sec. 1, Jianguo N. Rd., Jhongshan Dist.
Taipei City, Taiwan 10489
Taiwan

Re: K243045
Trade/Device Name: "BRAXX" Esophageal Brachytherapy Applicator (Model: BKMI2001, BKMI2002)
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: November 14, 2024
Received: November 14, 2024

Dear Anita Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JULIE SULLIVAN -S

Julie Sullivan, Ph.D.
Director
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243045

Device Name

"BRAXX" Esophageal Brachytherapy Applicator (Model: BKMI2001, BKMI2002)

Indications for Use *(Describe)*

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.

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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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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1. Submitter

Mailing Address	BRAXX Biotech Co. Ltd 6F., No.10, Songde Rd., Xinyi Dist Taipei City, 11076, Taiwan R.O.C
Contact Person	Wilson Lai
Phone:	886-658786670
E-mail:	Wilson.lai@braxx.com.tw
Date Prepared	2024.09.20

2 Subject Device

Proprietary Name:	“BRAXX” Esophageal Brachytherapy Applicator
Model Name	BKMI2001, BKMI2002
Common or usual 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 syst

3 Predicate Device

510(k) number:	K183332
Proprietary name:	“BRAXX” Esophageal Brachytherapy Applicator
Model Name	BKMI2001
Common or usual name	Esophageal Brachytherapy Applicator
Product Code	JAQ
Device Class	II

4 Device Description: [BKMI2001]
The device has 6 independently balloons. Each balloon corresponds to a specified needle free connector (valve). The #1 valve is connected to the most distal balloon and the #6 valve corresponds with the proximal balloon.

There is an indication balloon on each valve unit, which can indicate the inflated balloon. The distance between first marker printed on the main catheter and the distal tip is 19.8 cm. This device is disposable and designed for sterile and single use.

[BKMI2002]
The device has 8 independently balloons. Each balloon corresponds to a specified needle free connector (valve). The #1 valve is connected to the most distal balloon and the #8 valve corresponds with the proximal balloon. The distance between first marker printed on the main catheter and the distal tip is 40 cm. This device is disposable and designed for sterile and single use.

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.

6. Technological Characteristics and Substantial Equivalence Comparison with Predicate: A comparison of the device features, intended use, and other information demonstrates that the "BRAXX" Esophageal Brachytherapy Applicator (BKMI2001 and BKMI2002) is substantially equivalent to the predicate device as summarized in below table.

Device	"BRAXX" Esophageal Brachytherapy Applicator (K183332)	"BRAXX" Esophageal Brachytherapy Applicator	
Model	BKMI2001	BKMI2001	BKMI2002
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 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.	

Device	"BRAXX" Esophageal Brachytherapy Applicator (K183332)	"BRAXX" Esophageal Brachytherapy Applicator	
Model	BKMI2001	BKMI2001	BKMI2002
Key Components	A main catheter, balloons, controller part (with needle-free connectors).	A main catheter, balloons, controller part (with needle-free connectors and indication balloons).	
Mechanics of Action	Inflate the balloons by air or liquid via syringe. The inflatable balloons can expand the esophagus.	Inflate the balloons by air or liquid via syringe. The inflatable balloons can expand the esophagus.	
Number of Balloons	8	6	8
Balloon length	30	24	30
Indication ballon	No	Yes	No
Device length	1300	950	950
Sterilization method	EO	EO	

The subject device has the same intended use/indications for use as the predicate device (K183332). The subject device has the same manufacturing process, principle of operation, sterilization method as the predicate device (K183332). The difference of technological characteristics was verified by functional testing, biocompatibility testing and sterilization validation. The testing data demonstrates the proposed device performs as safely and effectively as the predicate device.

7. Performance Testing

Mechanical testing on balloon burst, fatigue, leakage and specification was verified and the test results pass the acceptance criteria. Mechanical testing on joint was verified and the test results pass the acceptance criteria.

The performance testing data demonstrate that this device meets the performance/ function specifications.

Mechanical Test	Acceptance Criteria
Ballon Burst test	> 30.0 Kpa, CV<10%
Balloon Fatigue test	> 30.0 Kpa, CV<10%
Balloon Diameter and Volume	SD <5 %, CV<5 %
Leakage test	No leakage
Tensile Strength test	>30N, CV<10 %

8.Biocompatibility testing

In vitro cytotoxicity, Skin Sensitization, Intracutaneous Irritation, Acute Systemic Toxicity and Pyrogen test were evaluated.

9.Sterilization Validation

Sterilization validation was conducted in accordance with ISO 11135:2014.

10. Conclusion

Based on the intended 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.