IsoAid, LLC
Timothy Bright
Sr. Director, Regulatory, Quality and Sterilization
7824 Clark Moody Blvd.
Port Richey, Florida 34668

July 15, 2025

Re: K242818
Trade/Device Name: IsoSphere
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide Brachytherapy Source
Regulatory Class: Class II
Product Code: KXK
Dated: October 23, 2024
Received: June 10, 2025

Dear Timothy Bright:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242818

Device Name

IsoSphere

Indications for Use *(Describe)*

IsoSphere is indicated for implantation after tumor resection in the breast to deliver the prescribed radiation dose to the tumor bed and any residual tumor in the remaining margins.

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
510(k) K242818
IsoSphere™

Company: IsoAid, LLC
7824 Clark Moody Blvd.
Port Richey, FL 34668
USA

Primary Contact: Timothy Bright, Sr. Director, RA/QA and Sterilization
1-866-710-5995

Date Prepared: July 14, 2025

Trade Name: IsoSphere™

Common Name: Brachytherapy Device

Classification: Class II

Regulation Number: 21 CFR 892.5730, Radionuclide Brachytherapy Source

Product Code: KXK

Panel: 90-Radiology

Predicate Device: K113210 - Advantage Strand/Advantage Load Brachytherapy Kit

Device Description:

The IsoSphere is a modification to the Advantage Strand™/Advantage Load™/Secure Strand Brachytherapy Kit cleared in 510(k) K113210 on August 10, 2012. Whereas the predicate device delivers radioactive brachytherapy seeds and spacers via numerous needles, one at a time in a linear design, the IsoSphere delivers multiple radioactive brachytherapy seeds and spacers within a Secure Strand sleeve to an excision site in the breast in one sphere-shaped configuration.

The IsoSphere is a 4 cm, spherical shaped device with hollow channels that contain radioactive brachytherapy seeds and spacers, depending on physician prescription. The device is composed of bioabsorbable copolymer (PLA) material, which is identical to the Secure Strand material. The IsoSphere is supplied with either Advantage I-125® seeds or Advantage Pd-103® seeds and spacers which are identical to those cleared in K113210. IsoSphere is supplied sterile for single use.

A sterile, single-use, non-radioactive 4cm Sizing Sphere is included in each package to assure a proper fit in the excision site. The package also contains one pair of sterile, radiation attenuating gloves.

Intended Use:

The IsoSphere device is intended to deliver radiation therapy to the tumor bed after tumor resection in the breast.

Indications for Use:

IsoSphere is indicated for implantation after tumor resection in the breast to deliver the prescribed radiation dose to the tumor bed and any residual tumor in the remaining margins.

Substantial Equivalence Comparison:

The intended use/indications for use of the IsoSphere device and predicate device are not identical, but similar. The differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both devices are implanted as a source of brachytherapy treatment to localized tumors in adult patients.

Predicate Device Comparison:

	IsoSphere™ 510(k) K242818 (Subject Device)	**Advantage Strand™/Advantage Load™ Brachytherapy Kit 510(k) K113210 (Predicate Device)**
Intended Use	The IsoSphere device is intended to deliver radiation therapy to the tumor bed after tumor resection in the breast.	Intended for the treatment of selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.
Indications for Use	IsoSphere is indicated for implantation after tumor resection in the breast to deliver the prescribed radiation dose to the tumor bed and any residual tumor in the remaining margins.	Indicated for tumors that are localized, unresectable, or have low to moderate radiosensitivity.
Intended Patient Population	Identical	Adults 18 years of age and older
Anatomical Site	Breast	Specific anatomical sites not stated
Radioactive Isotope(s)	Identical	Iodine-125 or Palladium-103 seeds
Delivery Method	Delivered via a 4cm, spherical shaped, bioabsorbable implantable device	Delivered through injection by 18-gauge needles
Visualization	Identical	Mammography, ultrasound, X-ray, CT

	IsoSphere™ 510(k) K242818 (Subject Device)	**Advantage Strand™/Advantage Load™ Brachytherapy Kit 510(k) K113210 (Predicate Device)**
Materials of construction	Identical	Polylactic Acid Copolymer (PLA) Titanium Seeds
Device Geometry	Spherical	Linear
Sterilization Method	Identical	Ethylene Oxide
Biocompatibility	Identical	Meets requirements for a permanent implant per ISO 10993-1
Single Use	Identical	Single Use
Shelf Life	Identical	30 Days
Permanent Implant	Identical	Yes
Principle of Operation	Delivers the prescribed dose of radiation via radioactive seeds in a spherical shape to the tumor bed after the tumor has been excised.	Multiple needles are used to deliver a strand of radioactive seeds at a precise distance to the targeted tumor site
Accessories Included with the Device	Packaging includes a sizing sphere and radiation attenuating gloves	No accessories included
Environment of Use	Identical	Healthcare Facility

Performance Testing:

The IsoSphere device has undergone the following testing and met all predetermined acceptance criteria:

- Biocompatibility for a permanent implant per ISO 10993-1
- Bacterial Endotoxin per ANSI/AAMI ST72
- Material Mediated Pyrogens Study per ISO 10993-11
- ETO Sterilization Validation per ISO 11135
- EO Residual Testing per ISO 10993-7
- Packaging Performance/Transit Testing per ISO 11607-1 & -2
- Type A Transportation Testing per 49 CFR Part 173
- MRI Compatibility Testing per FDA Guidance: Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, May 2021
- Stability Testing:
  Methodology:
  The IsoSphere test samples were packaged according to standard manufacturing procedures. The test samples were then twice exposed (2X) to the routine ETO sterilization process.
  Real-time aging of the test samples was performed by conditioning the test samples at controlled ambient environmental conditions (20 ± 5°C) for a minimum of 45 days to qualify a shelf life of 31 days. Following real-time aging, the test samples were subjected to sterile barrier integrity testing, seal strength testing, and product performance testing.

Acceptance Criteria and Results:
Sterile Barrier Integrity Testing: Testing was performed in accordance with ASTM F1886 Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection and ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration. No defects were detected in the seals, Tyvek lidding or plastic trays after completion of real-time aging.

Seal Strength Testing: Testing was performed in accordance with ASTM F2824-10 Standard Test Method for Mechanical Seal Strength Testing/or Round Cups and Bowl Containers with Flexible Peelable Lids. All test results met the seal strength requirement of 1.0 lbf/in - 6.0 lbf/in.

Product Performance Testing: Product performance testing was performed by measuring the dimensions of the samples, applying compressive force to the samples, and confirming the containment of the sealed sources. A compression test for each sample was performed at the specification of 2.6 lbf (reference ASTM F2051-00 Standard Specification for Implantable Saline Filled Breast Prosthesis).
After each compression point test, each sample was visually inspected for evidence of physical damage: breakage, bond separation, shifting or rupture of strands, seeds, or spacers. All bonds were intact, and no shifting or rupture of strands, seeds or spacers was detected.

- Design Integrity Testing:
  Methodology:
  Test samples were assembled per standard manufacturing procedures. The test samples were then twice exposed (2X) to the routine ETO sterilization process. Two sets of samples underwent real time aging; one set for a period of four months and one set for a period of six months.
  Testing was performed by measuring the dimensions of the samples, applying compressive force to the samples, and confirming the containment of the sealed sources. A compression test for each sample was performed at the specification of 2.6 lbf.

  Acceptance Criteria and Results:
  After each compression point test, each sample was visually inspected for evidence of physical damage: breakage, bond separation, shifting or rupture of strands, seeds, or spacers. All bonds were intact, and no shifting or rupture of strands, seeds or spacers was detected. All acceptance criteria were met.

No clinical data was included as part of this submission.

Conclusion:

Based on the non-clinical test results and comparison to the predicate device, the subject device is determined to be substantially equivalent to the predicate device.