November 07, 2024

INRAD Inc.
Heidi Halverson
RA/QA Manager
4375 Donker Court SE
Kentwood, Michigan 49512

Re: K240429
Trade/Device Name: Trilogy Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: October 7, 2024
Received: October 7, 2024

Dear Heidi Halverson:

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.11.07 17:51:29 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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.

510(k) Number *(if known)*
K240429

Device Name
Trilogy Tissue Marker

Indications for Use *(Describe)*
The Trilogy Tissue Marker is intended for use to attach to breast tissue at the surgical site during an open surgical breast biopsy or percutaneous breast biopsy to radiographically mark the location of the biopsy procedure, and be permanently visible under MRI, x-ray and ultrasound.

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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Trilogy Tissue Marker 510(k) Submission
510(k) Summary (K240429)

I. SUBMITTER

Sponsor/Manufacturer:
INRAD, Inc.
4375 Donker Court SE,
Kentwood, MI 49512, USA
Establishment Registration Number: 1835568

Contact Person:
Heidi Halverson
RA/QA Manager
INRAD, Inc.
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Kentwood, MI 49512, USA
Phone: (616) 301-7800
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Date Prepared:
01/31/2024

II. DEVICE

Name of Device: Trilogy Tissue Marker
Common or Usual Name: Tissue Marker / Implantable Radiographic Marker
Classification Name: Marker, Radiographic, Implantable (21 CFR 878.4300)
Regulatory Class: II
Product Code: NEU

III. PREDICATE DEVICE

The INRAD, Inc. Trilogy Tissue Marker [subject device] is substantially equivalent (SE) to the Sponsor's own predicate device:

EasyMark™ Tissue Marker, K183503
This predicate device has not been subject to a design related recall.

Reference Device: SelectCore Biopsy Device, K093256
This reference device has not been subject to a design related recall.
The INRAD, Inc. Trilogy Tissue Marker [subject device] is substantially equivalent (SE) to the INRAD, Inc. EasyMark Tissue Marker [predicate device] in terms of similar Indications for Use / Intended Use to mark

tissue during a percutaneous breast biopsy procedure and be permanently visible by x-ray, ultrasound and MRI.

Substantial equivalency (SE) of the subject device has also been based on substantially equivalent design, functionality, and performance characteristics as the predicate device.

IV. DEVICE DESCRIPTION

The Trilogy Tissue Marker is a sterile, single use device comprised of a disposable delivery device preloaded with a tissue marker. The disposable delivery device includes an introducer needle comprised of a plastic molded deployment handle, a thumb slide, a 14 ga. cannula with 1 cm depth marks and a push rod. The tissue marker is preloaded in the distal end of the cannula. Trilogy tissue markers are made of a non-resorbable polymer embedded with a nitinol shape, allowing for permanent visibility under ultrasound, x-ray, and MRI. This device offers the user the choice of three unique tissue marker shapes (i) Ring (ii) Cross (iii) Ribbon.

V. INTENDED USE / INDICATIONS FOR USE

The Intended Use and the Indications for Use are the same for the Trilogy Tissue Marker [subject device] and the INRAD, Inc. EasyMark Tissue Marker (K183503) [predicate device] with the exception of the addition of permanent visibility under MRI, x-ray and ultrasound to the Trilogy Tissue Marker [subject device].

[subject device]:
The Trilogy Tissue Marker is intended for use to attach to breast tissue at the surgical site during an open surgical breast biopsy or percutaneous breast biopsy to radiographically mark the location of the biopsy procedure, and be permanently visible under MRI, x-ray and ultrasound.

[predicate device]:
The EasyMark Tissue Marker is intended for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The INRAD, Inc. Trilogy Tissue Marker [subject device] is substantially equivalent (SE) to the INRAD, Inc. EasyMark Tissue Marker (K183503) [predicate device] based on the same functional and performance characteristics of the subject device when compared to the predicate device. The difference between the subject device's and predicate device's marker composition and delivery device's gauge size do not raise concerns of safety and effectiveness. To further analyze risks associated with the increased gauge size, an additional reference device known as SelectCore by INRAD has been included for reference.

A side-by-side comparison of the technological characteristics of design, components and materials of construction between the subject device and the predicate device, as well as the minor differences in the Intended Use/Indications for Use, do not raise concerns of safety and effectiveness. The comparisons supporting a determination of substantial equivalency (SE) are provided below.

Description	**Subject Device Trilogy Tissue Marker**	**Predicate Device EasyMark Tissue Marker (K183503)**	**Reference Device SelectCore Biopsy Device (K093256)**
Manufacturer	INRAD, Inc.	Same	INRAD, Inc.
Device Class	Class II	Same	Class II
Device Classification Name	Marker, Radiographic, Implantable	Same	Instrument, biopsy
Product Code	(NEU) – Marker, Radiographic, Implantable	Same	(KNW) – Gastroenterology-urology biopsy instrument
Regulation Number	21 CFR §878.4300	Same	21 CFR §876.1075
Indications for Use	The Trilogy Tissue Marker is intended for use to attach to breast tissue at the surgical site during an open surgical breast biopsy or percutaneous breast biopsy to radiographically mark the location of the biopsy procedure, and be permanently visible under MRI, x-ray and ultrasound.	The EasyMark Tissue Marker is intended for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.	The SelectCore device is intended for use in obtaining biopsies from soft tissues such as liver, breast, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. For breast biopsy this product is for diagnosis only - not for therapeutic use.

Description	**Subject Device Trilogy Tissue Marker**	**Predicate Device EasyMark Tissue Marker (K183503)**	**Reference Device SelectCore Biopsy Device (K093256)**
Marker Composition	Proprietary Polymer, Nitinol	Titanium 6Al-4V ELI - 3D Ribbon 316 LVM Stainless Steel - Anchor	N/A
Markers - Visualization Techniques	X-ray, Ultrasound, MRI	Same	N/A

Description	Subject Device Trilogy Tissue Marker	Predicate Device EasyMark Tissue Marker (K183503)	Reference Device SelectCore Biopsy Device (K093256)
Delivery Device Composition	Stainless Steel	Same	Stainless Steel
Needle Size	14ga	17ga	14ga
Packaging	Tyvek / poly pouch	Same	Thermoformed PETG tray w/ Tyvek Lid
Sterile	Yes	Same	Same
Method of Sterilization	Ethylene Oxide	Same	Same
Single-Use	Yes	Same	Same

VII. SUMMARY OF VERIFICATION DATA AND VERIFICATION TEST CONCLUSIONS

Non-Clinical Bench Performance Testing was conducted on the INRAD, Inc. Trilogy Tissue Marker [subject device] to confirm that the device meets all system requirements and is substantially equivalent (SE) to the INRAD, Inc. EasyMark Tissue Marker (K183503) [predicate device]. The following Verification Data was provided in support of the substantial equivalence (SE) determination.

- Performance Testing – Bench
    - Accuracy of Marker Deployment
    - Marker Deployment Force
    - Usability of the Device
    - Imaging Assessment
    - Safety and Compatibility in Magnetic Resonance (MR) Environment
    - Tissue Marker Migration Potential
    - Delivery Device Cannula Tensile Test
    - Delivery Device Push Rod Tensile Test
- Biocompatibility
- Sterilization
- Packaging
- Shelf Life

VIII. SUBSTANTIAL EQUIVALENCE SUMMARY / CONCLUSIONS:

The data generated from the results of the Verification Testing, Design Validation, and clinical literature, along with a side-by-side comparison of the technological characteristics of design, components, and materials of construction between the subject device and the predicate and reference device, demonstrate that the INRAD, Inc. Trilogy Tissue Marker [subject device] is as safe and effective and performs as well as the INRAD, Inc. EasyMark Tissue Marker (K183503) [predicate device].

The similar technological and performance characteristics for the proposed INRAD, Inc. Trilogy Tissue Marker [subject device] have been assessed to be substantially equivalent to the predicate device, and any differences in Intended Use/ Indications for Use do not raise concerns of safety and effectiveness when compared to the predicate or reference device. Therefore, the INRAD, Inc. Trilogy Tissue Marker [subject device] is substantially equivalent to the predicate device.