October 17, 2019

INRAD Inc.
Steve Field
CEO
4375 Donker Court SE
Kentwood, Michigan 49512

Re: K183503
Trade/Device Name: EasyMark Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: September 16, 2019
Received: September 18, 2019

Dear Mr. Field:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183503

Device Name
EasyMark Tissue Marker

Indications for Use *(Describe)*

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.

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.

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510(k) Summary

Date Prepared:	October 14, 2019
Applicant:	INRAD Inc. 4375 Donker Court SE, Kentwood, MI 49512, USA
Official Correspondent:	Steve Field Tel. (616) 301-7800 / Fax. (616) 301-7799 sfield@inradinc.com
Trade Name:	EasyMark™ Tissue Marker
Common Name:	Implantable Radiographic Marker
Classification Name:	Implantable Clip (21 CFR 878.4300, Product Code NEU)
Device Classification:	Class II
Predicate Device:	UltraClip® Tissue Marker, K993785

Device Description:

The EasyMark 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 17 ga. cannula with 1 cm depth marks and a push rod. The tissue marker is preloaded in the distal end of the cannula. This device offers the user the choice of two unique tissue markers (i) 316 LVM Stainless Steel Anchor shaped Marker (ii) Titanium 6Al-4V ELI Ribbon shaped Marker.

Indications for Use:

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.

Technological Comparison to Predicate Device:

The EasyMark Tissue Marker has the same indications for use, principles of operation, fundamental scientific technology, and performance as that of predicate device UltraClip. In addition, SelectCore was chosen as the reference device to support the biocompatibility of the EasyMark's delivery device. The patient contact materials of the EasyMark (cannula and push rod) and SelectCore (cannula and stylet) are made of same material 304 Stainless Steel and have the same manufacturing processes. Therefore, a biological evaluation was conducted for the EasyMark delivery device in reference to SelectCore, to establish the biocompatibility of the delivery device.

Description	**Subject Device** **EasyMark Tissue Marker**	**Predicate Device** **UltraClip Tissue Marker (K993785)**	**Reference Device** **SelectCore (K093256)**
Indications for Use	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 UltraClip® 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.
Device	The EasyMark Tissue Marker is a sterile, single use device comprised of a disposable delivery device preloaded with a tissue marker.	Same	The SelectCore is a sterile, single use device comprised of a disposable delivery device.
Marker	Titanium 6Al-4V ELI - 3D Ribbon shaped 316 LVM Stainless Steel - Anchor shaped	Titanium 6Al-4V ELI - Ribbon shaped 316 Stainless Steel - Ribbon shaped	N/A
Markers - Visualization Techniques	X-ray, MRI	Same	X-ray

Description	Subject Device EasyMark Tissue Marker	Predicate Device UltraClip Tissue Marker (K993785)	Reference Device SelectCore (K093256)
Delivery Device	Plastic Handle and Stainless Steel Cannula	Same	Plastic Handle and Stainless Steel Cannula
Needle Dimensions	17ga x 7cm 17ga x 10cm	17ga x 10cm	16ga x 10cm
Packaging	Poly-tyvek pouch	Same	Thermoformed tray (material PETG) - Tyvek lid
Method of Sterilization	Ethylene Oxide	Same	Same

Performance Data:

Non-clinical testing and evaluation was conducted to demonstrate that the EasyMark Tissue Marker is substantially equivalent to the predicate device. The following non-clinical testing and evaluations were performed:

- Performance Testing – Bench
  - Accuracy of Marker Deployment
  - Marker Deployment Force
  - Usability of the Device
  - Imaging Assessment (X-ray and MRI)
  - 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

Conclusion:

The results of non-clinical testing and evaluation demonstrates that the EasyMark Tissue Marker does not raise new concerns of safety or effectiveness and is substantially equivalent to the predicate device.