April 29, 2025

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

Re: K243886
Trade/Device Name: ExpressCore Biopsy Device
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: March 28, 2025
Received: March 28, 2025

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,

Jessica Carr -S

Jessica Carr, PhD
Assistant Director
DHT4A: Division of General 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)*
K243886

Device Name
ExpressCore Full Core Biopsy Device

Indications for Use *(Describe)*
The ExpressCore Full Core Biopsy Device is intended for use in obtaining biopsies from soft tissues.

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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ExpressCore Full Core Biopsy Device 510(k) Submission K243886

510(k) Summary

I. SUBMITTER

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

Contact Person:
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Date Prepared:
12/10/2024

II. DEVICE

Device Name(s):	ExpressCore Full Core Biopsy Device ExpressCore Full Core Biopsy Device w/ HiLiter®
Common or Usual Name	Biopsy Instrument
Classification Name:	Gastroenterology-urology Biopsy Instrument (21 CFR 876.1075)
Regulatory Class:	II
Product Code:	KNW

III. PREDICATE DEVICE

The INRAD, Inc. ExpressCore Full Core Biopsy Device [subject device] is substantially equivalent (SE) to the Sponsor's own predicate device:

Revolution Full Core Biopsy Device, K090611
This predicate device has not been subject to a design related recall.

Reference Devices:	EliteCore Full Core Biopsy Device, K112945 AccuCore Biopsy Device, K000612

The INRAD, Inc. ExpressCore Full Core Biopsy Device [subject device] is substantially equivalent (SE) to the INRAD, Inc. Revolution Full Core Biopsy Device (K090611) [predicate device] in terms of Indications for Use / Intended Use to obtain biopsies from soft tissues.

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 ExpressCore Device is a sterile, single patient use, hand held full core biopsy device comprised of a plastic handle and three stainless steel needle components that work in sequence to capture a full core biopsy sample. The device is capable of infinitely variable throw distance between 10 and 30mm and is equipped with multiple firing modes to accommodate procedural requirements and physician preference. Multiple device gauge size and needle option combinations have been developed from 12ga x 10cm to 18ga x 25cm.

V. INTENDED USE / INDICATIONS FOR USE

The Intended Use and the Indications for Use are the same for the ExpressCore Full Core Biopsy Device [subject device] and the INRAD, Inc. Revolution Full Core Biopsy Device (K090611) [predicate device] with the exception of specific tissue listings being omitted for ExpressCore.

[subject device]:
The ExpressCore Full Core Biopsy Device is intended for use in obtaining biopsies from soft tissues.

[predicate device]:
The Revolution Full Core Biopsy Device is intended for use in obtaining biopsies from soft tissues such as breast, liver, kidney, prostate, spleen, lymph nodes, and various soft tissue tumors.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The INRAD, Inc. ExpressCore Full Core Biopsy Device [subject device] is substantially equivalent (SE) to the INRAD, Inc. Revolution Full Core Biopsy Device (K090611) [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 gauge size, length options and packaging do not raise concerns of safety and effectiveness. To further analyze risks associated with the varying gauge sizes, length options and packaging, additional reference devices; EliteCore and AccuCore by INRAD have been included for reference.

The technological characteristics of design, function, and materials present in both the subject device and the predicate device has been evaluated. The comparisons supporting a determination of substantial equivalency (SE) are provided below.

Comparison Criteria	Subject Device ExpressCore Biopsy Device	Predicate Device Revolution Biopsy Device (K090611)	Reference Device EliteCore Biopsy Device (K112945)	Reference Device AccuCore Biopsy Device (K000612)
Manufacturer	INRAD, Inc.	Same	Same	Same
Device Class	Class II	Same	Same	Same
Device Classification Name	Biopsy Instrument	Same	Same	Same
Product Code	KNW	Same	Same	Same
Regulation Number	21 CFR §876.1075	Same	Same	Same
Indications for Use	This device is intended for use in obtaining biopsies from soft tissues.	This device is intended for use in obtaining biopsies from soft tissues such as breast, liver, kidney, prostate, spleen, lymph nodes, and various soft tissue tumors.	This device is intended for use in obtaining biopsies from soft tissues such as breast, liver, kidney, prostate, spleen, lymph nodes, and various soft tissue tumors.	This device is intended to be used as an automated instrument for percutaneous tissue core biopsy of several human organs including, but not limited to, prostate, kidney, liver, spleen, lung, breast, lymph nodes and different tumors.

Comparison Criteria	Subject Device ExpressCore Biopsy Device	Predicate Device Revolution Biopsy Device (K090611)	Reference Device EliteCore Biopsy Device (K112945)	Reference Device AccuCore Biopsy Device (K000612)
Handle Composition (non-patient contact)	ABS, Polycarbonate	ABS, TPE, Polyester, Acetal	ABS, TPE, Polyester, Acetal	Polycarbonate
Needle Composition (patient contact)	304 Stainless Steel	304 Stainless Steel 17-7 Stainless Steel	304 Stainless Steel 17-7 Stainless Steel	Same
Needle Processing	▪ Straightening ▪ Cut to length ▪ Grit blast ▪ Tip geometry ▪ Electropolish ▪ Depth marks ▪ Clean and passivate ▪ Finger bend ▪ Inspect and pack	Same	Same	Same + Notch grind (stylet) - Finger bend
Needle Gauge Size	12ga, 14ga, 16ga, 18ga	14ga	18ga	Same
Needle Lengths	10cm, 15cm, 20cm, 25cm	10cm, 15cm	Same	Same
Needle Echogenicity	HiLiter Stylet (select product codes)	Same	Same	Grit blasted cannula
Throw Length	Variable 10-30mm	Variable 13-25mm	Variable 13-25mm	Fixed
Mechanism of Throw Adjustment	Thumb Wheel	Same	Same	N/A
Mechanism of Arming	Dual Stroke	Same	Same	Single Stroke
Firing Modes	Semi or Automatic	Same	Same	Single Action
Packaging Configuration	Tyvek / PE pouch	Tyvek / PETG Tray	Tyvek / PETG Tray	Same
Sterile	Yes	Same	Same	Same
Method of Sterilization	Ethylene Oxide	Same	Same	Same
Single-Use, Disposable	Yes	Same	Same	Same

VII. SUMMARY OF VERIFICATION DATA AND VERIFICATION TEST CONCLUSIONS

Non-Clinical Bench Performance Testing was conducted on the INRAD, Inc. ExpressCore Full Core Biopsy Device [subject device] to confirm that the device meets all system requirements and is substantially equivalent (SE) to the INRAD, Inc. Revolution Full Core Biopsy Device (K090611) [predicate device]. The following Verification Data was provided in support of the substantial equivalence (SE) determination.

- Performance Testing – Simulated Use / Bench
    - Usability of the Device
    - Biopsy Sample Collection
    - Finger Cannula Tensile Test
    - Spoon Cannula Tensile Test
    - Stylet Tensile Test
    - Representative Tissue Sampling
- Biocompatibility
- Sterilization
- Packaging
- Shelf Life

VIII. SUBSTANTIAL EQUIVALENCE SUMMARY / CONCLUSIONS:

The data generated from the results of the Verification Testing, Design Validation, and evaluations, along with a side-by-side comparison of the technological characteristics of design, function, and materials between the subject device and the predicate and reference devices, demonstrate that the INRAD, Inc. ExpressCore Full Core Biopsy Device [subject device] is as safe and effective and performs as well as the INRAD, Inc. Revolution Full Core Biopsy Device (K090611) [predicate device].

The similar technological and performance characteristics for the proposed INRAD, Inc. ExpressCore Full Core Biopsy Device [subject device] have been assessed to be substantially equivalent to the predicate device, and the slight differences do not raise concerns of safety and effectiveness when compared to the predicate or reference devices. Therefore, the INRAD, Inc. ExpressCore Full Core Biopsy Device [subject device] is substantially equivalent to the predicate device.