January 10, 2025

Triopsy Medical, Inc.
% John Mann
Chief Executive Officer
Insight Navigation LLC
501 N Ford Street
Golden, Colorado 80403

Re: K242228
Trade/Device Name: Triopsy Actuator (TMSDGB);
Triopsy Biopsy Needle (BN-1825-36-01);
Triopsy Biopsy Needle (BN-1825-55-01)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: December 9, 2024
Received: December 9, 2024

Dear John Mann:

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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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.

Submission Number *(if known)*

K242228

Device Name

Triopsy Actuator (TMSDGB);
Triopsy Biopsy Needle (BN-1825-36-01);
Triopsy Biopsy Needle (BN-1825-55-01)

Indications for Use *(Describe)*

The Triopsy Biopsy System (instrument and needles) is intended for use in obtaining biopsies from the prostate.

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) #: K242228

510(k) Summary

Prepared on: 2024-12-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Triopsy Medical, Inc.
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Applicant Contact Telephone	(804) 677-8527
Applicant Contact	Dr. David Bostwick
Applicant Contact Email	dbostwick@triopsy.com
Correspondent Name	Insight Navigation LLC
Correspondent Address	501 N Ford St Golden CO 80403 United States
Correspondent Contact Telephone	7208082416
Correspondent Contact	Mr. John Mann
Correspondent Contact Email	john@insightnav.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Triopsy Actuator (TMSDGB); Triopsy Biopsy Needle (BN-1825-36-01); Triopsy Biopsy Needle (BN-1825-55-01)
Common Name	Gastroenterology-urology biopsy instrument
Classification Name	Instrument, Biopsy
Regulation Number	876.1075
Product Code(s)	KNW, FCG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K934370	Magnum Reusable Core Biopsy Instrument	KNW
K934371	Magnum Needle	FCG

Device Description Summary

21 CFR 807.92(a)(4)

The Triopsy Medical Actuator and Biopsy Needle is comprehensive system that aids in the diagnosis and treatment planning of prostate cancer. The system utilizes an actuator instrument and biopsy needle (disposable) with the intention of gathering prostate tissue and properly identifying its pathology. The needle collects full-length, unbroken apex-to-base core samples with patented ridges that hold and protect the sample's integrity. The actuator allows for variable sample lengths for each area of the prostate to be biopsied—increasing accuracy and patient safety by avoiding under or overshooting.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Triopsy Biopsy System (instrument and needles) is intended for use in obtaining biopsies from the prostate.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject and the predicate device have similar indications for use statements and intended use for acquisition of core biopsy samples, device is prescription only.

Technological Comparison 21 CFR 807.92(a)(6)

There are no differences between the indications for use of the predicate, Bard Magnum Reusable Core Biopsy Instrument & Bard Magnum Disposable Biopsy Core Needle (K934370 & K934371) and the subject device The Triopsy™ Reusable Biopsy Actuator & Triopsy™ Single-Use Biopsy Needle. The primary differences between the predicate Bard Magnum Reusable Core Biopsy Instrument & Bard Magnum Disposable Biopsy Core Needle (K934370 & K934371) and the subject device The Triopsy™ Reusable Biopsy Actuator & Triopsy™ Single-Use Biopsy Needle are the variable penetration depth setting of the Triopsy™ Actuator and the sample length notch of the Triopsy™ Needles. Based on substantial equivalence testing neither of these differences raise new questions of safety or efficacy.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The performance requirements of the device were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology (February 1993) including:

- Depth Projection
- Mechanical Durability
- Penetration
- Activation Force (Spring)
- Sample Extraction

In Addition, Following FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016), the human factors studies were conducted with the intended user population, use environment, and use scenarios to simulate clinical conditions. Results of the human factors testing demonstrate validation of the device per the intended use.
In addition,

Not Applicable

The Triopsy™ Reusable Biopsy Actuator & Triopsy™ Single-Use Biopsy Needle was verified and validated in accordance with 21 CFR §820.30. Testing was completed to demonstrate substantial equivalence and that any technological differences do not raise new or different questions of safety and effectiveness. The device successfully passed all of the testing and the results demonstrate the device is safe, effective, and performs as well or better than the predicate device. The differences between the predicate and the subject device do not introduce or raise concerns regarding the safe and effective use of the subject device.
The subject device, Triopsy™ Reusable Biopsy Actuator & Triopsy™ Single-Use Biopsy Needle, is substantially equivalent to the legally marketed predicate device, Bard Magnum Reusable Core Biopsy Instrument & Bard Magnum Disposable Biopsy Core Needle (K934370 & K934371) with respect to the intended use/indications for use, target populations, treatment method, and technological characteristics.