NeoDynamics AB
% Leann Latham
Regulatory Consultant
M Squared Associates,Inc.
127 West 30th Street, 9th Floor
New York, New York 10001

September 8, 2022

Re: K220595
Trade/Device Name: NeoNavia Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: August 1, 2022
Received: August 3, 2022

Dear Leann Latham:

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,

Colin Chen
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220595

Device Name
NeoNavia Biopsy System

Indications for Use *(Describe)*
The NeoNavia biopsy system is intended for obtaining tissue samples from both breast lesions and axillary lymph nodes for diagnostic analysis of breast abnormalities.

The FlexiPulse and VacuPulse probes are intended to provide tissue from breast lesions and axillary lymph nodes for histologic examination.

The NeoNavia biopsy system is to be used only by healthcare professionals in hospitals or healthcare facilities.

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.

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Section 005: 510k Summary

The following information is provided as required by 21 CFR § 807.87 for NeoNavia Biopsy System 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

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Date of Submission: February 28, 2022

Proprietary Name: NeoNavia Biopsy System

Common Name: Instrument, Biopsy

Regulatory Class: Class II

Regulation: 21 CFR 876.1075

Product Codes: KNW, FCG

Predicate Devices: Primary Device Trade Name: Mammotome elite® Biopsy System
Device Company: Devicor® Medical Products, Inc.
510(k) Number: K153709

Device Description :
NeoNavia® biopsy system is designed to obtain tissue samples from breast lesions or axillary lymph nodes for histological evaluation. The system is composed of a base unit, a driver and two different types of sterile single use probes. Each probe type (also referred to as needle) utilizes pulses with the intention to improve precision and control when inserting and positioning the biopsy needle in a suspicious lesion. NeoNavia® must be operated together with ultrasound imaging guidance.

Intended Use

The NeoNavia biopsy system is intended for obtaining tissue samples from both breast lesions and axillary lymph nodes for diagnostic analysis of breast abnormalities.

Indications for Use:

The FlexiPulse and VacuPulse probes are intended to provide tissue from breast lesions and axillary lymph nodes for histologic examination.

The NeoNavia biopsy system is to be used only by healthcare professionals in hospitals or healthcare facilities.

Technological characteristics, comparison to predicate device:

Table 1: Comparison table of NeoNavia and the predicates

Characteristics	NeoNavia® Biopsy System (subject device)	Mammotome elite® Biopsy System (Primary predicate)	Differences and Comments
Description	NeoNavia® biopsy system is designed to obtain tissue samples from breast lesions or axillary lymph nodes for histological evaluation. The system is composed of a base unit, a driver and two different types of sterile single use probes.	Mammotome elite® Biopsy System consists of a reusable Holster and a single-patient use, sterile Probe that is used with ultrasound imaging guidance to excise and collect diagnostic samples with a single insertion of the Probe.	
510(k) number	TBD	K153709	
Product Code	KNW, FCG (proposed)	KNW	
Intended Use	The NeoNavia biopsy system is intended for obtaining tissue samples from both breast lesions and axillary lymph nodes for diagnostic analysis of breast abnormalities.	The Mammotome elite® Biopsy System is intended to provide breast or axillary lymph node tissue samples for diagnostic analysis of imaged or palpated breast abnormalities.	Same, to provide breast tissue and lymph node samples for diagnostic analysis.

Characteristics	NeoNavia® Biopsy System (subject device)	Mammotome elite® Biopsy System (Primary predicate)	Differences and Comments
Indications for Use	The FlexiPulse and VacuPulse probes are intended to provide tissue from breast lesions and axillary lymph nodes for histologic examination. The NeoNavia biopsy system is to be used only by healthcare professionals in hospitals or healthcare facilities.	The Mammotome elite® Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. • The Mammotome elite® Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. • The Mammotome elite® Biopsy System is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality. The extent of a histologic abnormality cannot always be readily determined from the palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it	NeoNavia is not intended for complete removal of the imaged abnormality whereas Mammotone is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. This difference does not affect NeoNavia's intended use or indications for use for obtaining tissue samples from both breast lesions and axillary lymph nodes for diagnostic analysis of breast abnormalities.

Characteristics	NeoNavia® Biopsy System (subject device)	Mammotome elite® Biopsy System (Primary predicate)	Differences and Comments
		is essential that the tissue margins be examined for completeness of removal using standard surgical procedures. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the Mammotome elite® Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.	
Intended users	Healthcare professionals (The NeoNavia system is to be used only by healthcare professionals trained in subcutaneous biopsy procedures	Healthcare professionals (Minimally invasive procedures should be performed only by persons having adequate training and	Same

Characteristics	NeoNavia® Biopsy System (subject device)	Mammotome elite® Biopsy System (Primary predicate)	Differences and Comments
	guided by ultrasound imaging equipment.)	familiarity with minimally invasive techniques.)	
Image guidance modality	Ultrasound	Ultrasound	Same
Patient contacting materials	Stainless steel	Stainless steel	Same
Handheld procedure?	Yes	Yes	Same
Method of needle insertion and advancement	Manual positioning Optional short longitudinal movement to aid advancing the needle millimeter by millimeter.	Manual positioning	NeoNavia may be used manually and with short longitudinal movement that provides greater control over manual positioning.
Vacuum	Vacuum Assisted System	Vacuum Assisted System	Same
Single use disposable vs Reusable device	Single use, disposable biopsy probe; reusable driver and base unit	Single use, disposable biopsy probe; reusable driver	Same

Table 2: Comparison of NeoNavia VacuPulse probe to predicate

Characteristics	NeoNavia VacuPulse configurations	Mammotome elite® Biopsy System	Differences and Comments
Marketed needle size	10 Gauge	10 & 13 Gauge	Mammotome has an additional smaller size needle.
Method of tissue sampling	Vacuum assisted side-cut needle with rotating inner cutting cannula advanced forward to sever tissue sample.	Vacuum assisted side-cut needle with rotating inner cutting cannula advanced forward to sever tissue sample.	Same
Method of sample collection	Vacuum transport to sample collection basket.	Vacuum transport to sample collection basket.	Same

Characteristics	NeoNavia VacuPulse configurations	Mammotome elite® Biopsy System	Differences and Comments
	Multiple samples possible.	Multiple samples possible.	

Table 3: Comparison of NeoNavia Flexipulse probe to the predicates

Characteristics	NeoNavia FlexiPulse configurations	Mammotome elite® Biopsy System	Differences and Comments
Marketed needle size	14 Gauge	10 & 13 Gauge	Difference in needle sizes. No significant impact to substantial equivalence per testing performed with FlexiPulse needle as compared to Mammotome 10G needle. Ref. NeoNavia Biopsy System Needle Size Rational report
Method of tissue sampling	Front loaded vacuum assisted needle with rotational severing capability, advanced forward millimeter by millimeter using short longitudinal movement.	Vacuum assisted side-cut needle with rotating inner cutting cannula advancing forward to sever tissue sample.	NeoNavia needle is front loaded compared to side cut. Safety and performance of needles/probes validated by animal testing.
Method of sample collection	Single sample inside front loaded needle.	Vacuum transport to sample collection basket. Multiple samples possible.	FlexiPulse collects a single sample whereas Mammotome collects multiple samples.

Performance testing:

Sterilization, Shelf Life and Packaging

The VacuPulse and FlexiPulse probes of the NeoNavia Biopsy System are provided sterile. Sterilization validation, sterile packaging validation and shelf life testing have been performed for the sterile disposable probes.

Biocompatibility Testing

Biocompatibility testing results for cytotoxicity, irritation, sensitization, acute systemic toxicity and materials mediated pyrogenicity indicate the NeoNavia VacuPulse probe is safe for its indicated use.

Software and Security

The Level of Concern associated with the software of the NeoNavia Biopsy System is considered to be Moderate. Testing was completed in accordance with the guidance document, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Final, 2005).

Electromagnetic Compatibility and Electrical Safety

Electromagnetic compatibility and electrical safety testing was performed on the NeoNavia Biopsy System.

Bench Testing

Various bench testing was performed for verification and validation of the NeoNavia Biopsy System. Testing included comparison performance testing, usability validation and performance verification testing.

Animal Testing

Animal testing was conducted to compare the NeoNavia VacuPulse, NeoNavia Flexipulse and Mammotome biopsy devices. Biopsy samples from sheep and pigs were evaluated for biopsy sample quality (gross qualitative assessment and via histopathology), acute bleeding rate, and hematoma.

Conclusion

Based on the information provided the NeoNavia Biopsy System is substantially equivalent in terms of indications for use, technology and performance to the predicate devices.