September 25, 2023

Praxis Medical, LLC
% Paul Dryden
Consultant
Praxis Medical, LLC c/o ProMedic LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K230778
Trade/Device Name: EndoCore
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: September 25, 2023
Received: August 29, 2023

Dear Paul Dryden:

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.

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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 on last page.

510(k) Number *(if known)*

K230778

Device Name

Praxis Medical EndoCore

Indications for Use *(Describe)*

The Praxis Medical EndoCore is used with ultrasound endoscope to sample targeted submucosal and extramural lesions of the tracheobronchial tree. For any patient 18 years and older requiring tissue sampling.

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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510(k) Summary

Date Prepared:	21-Sep-2023
	Praxis Medical, LLC 500 N Willow Ave. Ste 101 Tampa, FL 33606 Tel – 727-482-1602
Sponsor Contact:	John Fisher, MD - CEO
Submission Contact:	Paul Dryden – ProMedic Consulting, LLC
Proprietary or Trade Name:	Praxis Medical EndoCore
Common/Usual Name:	Bronchoscope Accessory
Classification Name:	Product Code – KTI Bronchoscope (Flexible or Rigid) And Accessories
Predicate Device:	Endobronchial Ultrasound Aspiration Needle – K213060
Device Description:	The EndoCore is intended to be used with endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the tracheobronchial tree.
Principle of Operation:	EndoCore is inserted through an endoscope working channel to the target lesion area. Once in place, the healthcare provider pushes a button to activate a battery powered internal motor to rotate the needle to facilitate cellular material collection.
Indications for Use:	The Praxis Medical EndoCore is used with ultrasound endoscope to sample targeted submucosal and extramural lesions of the tracheobronchial tree. For any patient 18 years and older requiring tissue sampling.

Table 1: Comparison of Subject vs. Predicate and Reference Devices

	Subject Device Praxis Medical EndoCore	**Predicate Device Micro-Tech (Nanjing) Co., Ltd. Endobronchial Ultrasound Aspiration Needle**	**Reference Device Praxis Medical CytoCore**	**Comparison**
K#	K230778	K213060	K200278	-
Product Code	KTI	KTI	KNW	-
CFR	21 CFR 874.4680	21 CFR 874.4680	21 CFR 876.1075	-
Regulation Name	Bronchoscope (Flexible or Rigid) And Accessories	Bronchoscope (Flexible or Rigid) And Accessories	Instrument, Biopsy	Similar
Indications for Use	The Praxis Medical EndoCore is used with ultrasound endoscope to sample targeted submucosal and extramural lesions of the tracheobronchial tree. For any patient 18 years and older requiring tissue sampling	The Endobronchial Ultrasound Aspiration Needle is used with ultrasound endoscope to sample targeted submucosal and extramural lesions of the tracheobronchial tree.	The CytoCore is a device to hold a syringe for performing a biopsy of an identified mass with one hand.	We have included the CytoCore as a reference device because of the technological difference in needle movement between the subject and predicate device. The rotational needle movement of the subject device is identical to the reference device.
Environment of Use	Hospitals, sub-acute, clinics and physician office settings.	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope.	Hospitals, sub-acute, clinics and physician office settings.	Similar
Components	Needle Assembly: Handle, Sheath, Needle, and Stylet Syringe with stopcock Adapter	Needle Assembly: Handle, Sheath, Needle, and Stylet Syringe with stopcock Adapter	The Praxis Medical CytoCore is a syringe-holding device for performing a biopsy of soft tissue for diagnostic sampling. CytoCore does not contain a needle.	Similar – The subject device and predicate device have the same components in that each device includes a needle, syringe with stopcock and adapter. The reference device is a syringe holding device and is only referenced to support the rotating mechanism.

	Subject Device Praxis Medical EndoCore	Predicate Device Micro-Tech (Nanjing) Co., Ltd. Endobronchial Ultrasound Aspiration Needle	Reference Device Praxis Medical CytoCore	Comparison
Principle of Operation	EndoCore is inserted through an endoscope working channel to the target lesion area. Once in place, the healthcare provider can activate the device to rotate the needle to help facilitate cellular material collection. The syringe is used to collect the tissue sample. Standard vacuum syringe techniques may be applied for biopsy.	The predicate device is inserted through an EBUS endoscope working channel to the target lesion area. The syringe is used to collect the tissue sample. Standard vacuum syringe techniques may be applied for biopsy.	A needle is connected to a syringe and then the needle inserted into a lesion. The syringe plunger is retracted to create suction while the subject device contains a battery-powered internal motor that rotates the needle. This rotation harvests the cellular material in a similar way as the in/out motion.	Both the subject device and predicate device collect the tissue sample with vacuum from a syringe. The subject device uses an internal motor to rotate the needle to help collect cellular tissue, whereas the predicate uses a to-and-fro motion to collect cellular tissue. This cellular material collection technology (rotating needle) is the same as cleared under the reference device (K200278).
Patient Population	Any patient 18 years or older requiring tissue sampling.	No information available.	Any patient population requiring the harvest of cellular material.	Although the predicate device did not indicate a patient population in its 510(k) summary, we believe this stated patient population is appropriate.
Mode of Action	Single puncture with needle rotation, though multiple punctures are possible, if required by the clinician.	Single/multiple puncture and aspirate.	Single puncture with needle rotation, though multiple punctures are possible, if required by the clinician.	The predicate requires at least a single puncture and possibly multiple punctures to gather cellular material. The subject device can be used as a single puncture, then the needle rotates (identical to the reference device) to collect cellular material.
Single Use	Yes	Yes	Yes	Similar

	Subject Device Praxis Medical EndoCore	Predicate Device Micro-Tech (Nanjing) Co., Ltd. Endobronchial Ultrasound Aspiration Needle	Reference Device Praxis Medical CytoCore	Comparison
Method of Sample Collection	Standard vacuum syringe technique for biopsy with a rotating needle to facilitate cellular material collection.	Standard vacuum syringe technique for biopsy.	Standard vacuum syringe technique for biopsy with a rotating needle to facilitate cellular material collection.	EndoCore uses a rotating needle with a vacuum syringe to collect cellular tissue, whereas the predicate used a standard needle and a vacuum syringe. The same cellular material collection technology for the subject device was cleared under reference K200278.
Method of needle insertion and advancement	Manual positioning.	Manual positioning.	Manual positioning.	Similar
Image guidance modality	Ultrasound	Ultrasound	N/A	Similar
Compatible Endoscope Working Channel (mm)	Minimum diameter of 2.1	Minimum 2.0	N/A	The minimal difference in working channel diameter does not raise any safety or efficacy concerns.
Needle Material	Nitinol	Nitinol	No needle provided.	Similar
Needle Gauge	22G only	19G, 22G, 25G	N/A	Similar
Needle Diameter (mm)	0.7 only	1.1, 0.7, 0.5	N/A	Similar
Needle Tip	Bevel only	Bevel, Trident	N/A	Similar
Stylet OD (inch)	0.016	0.030, 0.016, 0.011	N/A	Similar
Maximum Needle Length (mm)	60	40	N/A	The size difference in maximum needle length does not raise any safety or efficacy concerns.
Working Length (mm)	665-725	720-760	N/A	The size difference in working length does not raise any safety or efficacy concerns.

	Subject Device Praxis Medical EndoCore	Predicate Device Micro-Tech (Nanjing) Co., Ltd. Endobronchial Ultrasound Aspiration Needle	Reference Device Praxis Medical CytoCore	Comparison
Maximum Insertion Portion Diameter /mm	1.6	1.8	N/A	The minimal difference in maximum insertion portion diameter does not raise any safety or efficacy concerns.
Supplied Sterile	Yes	Yes	Yes	Similar
Packaging	Device is placed in a 1073B uncoated Tyvek pouch, then sterilized.	Needle assembly, syringe with stopcock and adapter are placed in tray with snap downs. Tray placed in pouch. Pouch placed in case box for sterilization.	N/A	Similar
Shelf Life	One year	Three years	N/A	The difference in shelf life does not raise any new safety or efficacy questions.
Biocompatibility	Tested per ISO 10993-1	Tested per ISO 10993-1	Tested per ISO 10993-1	Similar
Sterilization	Gamma Sterilized using the VDmax25 method SAL:10-6	EO Sterilized SAL:10-6	N/A	The difference in sterilization method does not raise any new safety or efficacy questions.
Labeling	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	Similar

Non-clinical Testing
Performance testing demonstrated that the subject device met its acceptance criteria. Testing included:

Biocompatibility
- ISO 10993-1: Biological Evaluation
- ISO 10993-5: Cytotoxicity
- ISO 10993-10: Sensitization
- ISO 10993-10: Intracutaneous Reactivity
- ISO 10993-11: Acute Systemic Toxicity
- ISO 10993-11: Material-Mediated Pyrogenicity
- Bacterial Endotoxin

Electromagnetic Compatibility and Electrical Safety
- IEC 60601-1: 2005 + A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2020 Collateral standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-6:2010+AMD1:2013 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Bench Testing
- ISO 80369-1:2018 - Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements
- ISO 80369-7:2021 - Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20:2015 - Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods
- ISO 11070:2014 - Sterile single-use intravascular introducers, dilators and guidewires
- Mechanical, Drop and Transit Testing
- EndoCore EBUS Adapter Leakage
- Needle Wobble
- Radiopacity
- Scope Compatibility
- Ultrasound Compatibility

Intended Use/ Indications for Use
The indications for use for the subject device are identical to the predicate device – Endobronchial Ultrasound Aspiration Needle – K213060.

Technological Characteristics and Principles of Operation
The technological characteristics and principle of operation are similar, with the exception of needle movement (to- and fro- motion vs. needle rotation) to the device – Endobronchial Ultrasound Aspiration Needle – K213060.

As stated, the subject device uses an internal motor to rotate the needle to help collect cellular tissue. This cellular material collection technology (rotating needle) is the same as cleared under the reference device (K200278).

Environment of Use –
The environment of use is identical.
Discussion – The environments of use are identical to the predicate – Endobronchial Ultrasound Aspiration Needle – K213060.

Patient Population –
Though the predicate device does not list a specific patient population, we have included our proposed patient population. For any patient 18 years and older requiring tissue sampling
Discussion – The patient population is equivalent to the predicate device – Endobronchial Ultrasound Aspiration Needle – K213060.

Conclusion
Based upon the performance testing and comparison of technological characteristics, indications for use, the subject device is substantially equivalent to the legally marketed predicate device – Endobronchial Ultrasound Aspiration Needle – K213060.