March 31, 2020

Praxis Medical, LLC
℅ Paul Dryden
ProMedic LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K200278
Trade/Device Name: Praxis Medical CytoCore
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: February 3, 2020
Received: February 4, 2020

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 (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,

Long Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200278

Device Name

Praxis Medical CytoCore

Indications for Use *(Describe)*

The CytoCore is a device to hold a syringe for performing a biopsy of an identified mass with one hand.

Type of Use *(Select one or both, as applicable)*

XX 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: 27-Mar-2020

I Submitter

Praxis Medical LLC
500 N Willow Ave #101
Tampa, FL 33606
T - (813) 545-8607

Submitter Contact: John Fisher, M.D.
CEO

Submission Correspondent: Paul Dryden
ProMedic, LLC

II Device

Proprietary or Trade Name:	Praxis Medical CytoCore
Common/Usual Name:	Instrument, Biopsy
Classification Name:	Instrument, Biopsy (21 CFR 876.1075)
Regulatory Class:	II
Product Code:	KNW

III Predicate Device: K972496 – TAO Aspirator and Plastic Finger

IV Device Description:

The Praxis Medical CytoCore is a syringe-holding device for performing a biopsy of soft tissue for diagnostic sampling. It is equipped with a scissor-slide mechanism for drawing back the syringe plunger to create suction, and an internal motor oscillates the needle to facilitate cellular material harvesting. The device places the hand relatively close to the needle tip while the hand is in a position of natural function, providing greater tactile sensation of the texture of the lesion and enabling accurate needle placement using fine motor control of the hand. The device enables an operator to place a needle into a target area to harvest cells.

V Indications for Use:

The Praxis Medical CytoCore is a device to hold a syringe for performing a biopsy of an identified mass with one hand.

Environments of use: Hospitals, sub-acute, clinics and physician office settings.

VI Comparison of Technological Characteristics and Performance with the Predicate

Table 1 is a comparison – Subject Device vs. the Predicate, K972496 including technological characteristics and performance.

Table 1: Comparison of the CytoCore vs. Tao Aspirator

Attribute	Predicate Device K972496 – TAO Aspirator and Plastic Finger	Subject Device Praxis Medical CytoCore K200278	Comparison	Does the difference raise new questions of safety and effectiveness?
K#	K972496	TBD	N/A	N/A
Classification	KNW – Gastroenterology-Urology Biopsy Instrument 21 CFR 876.1075	KNW – Gastroenterology-Urology Biopsy Instrument 21 CFR 876.1075	Same	No
Indications for Use	The TAO Aspirator™ is a device to hold a 10cc syringe for performing fine needle aspiration of a palpable mass with one hand, while stabilizing the mass to be aspirated with the other hand. It is equipped with a release button for automatically drawing back the syringe plunger, and is designed to be held in a pencil-grip manner. This device places the hand relatively close to the needle tip while the hand is in a position of natural function, enabling the needle movement using fine motor control of the hand.	The Praxis Medical CytoCore is a device to hold a syringe for performing fine needle aspiration of an identified mass with one hand.	Similar	No. We have removed the language from the predicate device detailing how the device is used. This was discussed during Q191469 and FDA agreed that this language was outdated.
Principle of Operation	A needle is connected to a syringe and inserted into a lesion. The syringe plunger is retracted to create suction while the operator moves the needle in an in-and-out motion within the lesion at a rate of 5-10 times per second. The needle does not rotate.	A needle is connected to a syringe and inserted into a lesion. The syringe plunger is retracted to create suction while the subject device contains a battery-powered internal motor that rotates at 300 rpm the needle in an alternating clockwise / counterclockwise rotation. This altering rotation harvests the cellular material in a similar way as the in/out motion.	The subject device, can be used with the in-and-out motion similar to the predicate. It differs in that a battery powers a motor that rotates the needle.	Similar Like the predicate the technique can also be the in/out motions, but the alternating rotation of the needles has shown to provide equivalent cellular harvesting. The technology of needle rotation does not raise new concerns of safety that could not be demonstrated as safe and equivalent to the predicate.

Attribute	Predicate Device K972496 – TAO Aspirator and Plastic Finger	Subject Device Praxis Medical CytoCore K200278	Comparison	Does the difference raise new questions of safety and effectiveness?
Patient Population	Any patient population requiring the harvest of cellular material	Any patient population requiring the harvest of cellular material	Similar	No
Environments of use	Hospitals, sub-acute, pre-hospital	Hospitals, sub-acute, pre-hospital	Similar	No
Compatibility with environment and other devices	Unknown	Typically, a CT or ultrasound ("imaging") is used to locate the tissue/mass, however, there is no interaction between a CT/Ultrasound and the subject device	Similar	No
Prescriptive	Yes	Yes	Similar	No
Single patient use, disposable	Yes	Yes	Similar	No
Basic components	It is unclear if the predicate supplied a needle, however, the device is a handle to hold a 10cc syringe for the purpose of fine needle aspiration	The end user supplies the needle as directed within this submission (22-25 gauge), and a powered handle – the subject device. All items are single use, disposable	Similar	No
Needle Gauge	Unknown	22-25 gauge	Similar	Performance testing included a 22-25-gauge needle with both the subject and predicate devices
Materials	Unknown	Medical-grade plastic	Similar	No
Patient Contact	Unknown if the needle was included as part of the system, but the device has no patient contact	The CytoCore has no patient contact. The user supplied needle contacts the patient.	Similar	The user supplied needles were previously cleared by FDA and information can be found in Section 18 with 510(k) numbers.
Power Source	Non-powered, user moves the needle in an in-and-out motion to harvest cellular material	DC-powered; internal built-in battery	Different	Use of a battery operated motor to rotate the needle does not raise different risks that cannot be addressed via testing.

VII Performance Data

The following performance data were provided in support of the substantial equivalence determination.

- Accelerated ageing including environmental
  - 1-year shelf-life
  - Pre- and post-aging of the subject device
  - Drop Testing
- Biocompatibility of materials
  - The subject device has no patient contact.
  - The user supplies the needle
- Performance Testing
  - Needle compatibility
  - Comparative cellular harvest ability of the subject vs. predicate device

Performance Testing – Pre and Post Aging
Finished, final samples were subjected to various conditioning scenarios. The samples were tested at the equivalent of 12 months of accelerated aging.

Drop Testing
The samples were removed from their shipping box and allowed to fall freely twice from each of three different starting orientations (for a total of 6 drops) from a height of 1m onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m3) lying flat on a concrete or a similar rigid base. Samples passed.

Comparative Performance Testing – Subject vs. Predicate Device
Fifteen licensed physicians utilized the subject device and the predicate. Comparative cellular harvesting was then evaluated and scored with of the subject device vs. the predicate averaging 1.85 (predicate) vs. 2.59 for CytoCore.
Discussion – The results demonstrate that the subject device was able to harvest or collect an equivalent to more celluar materials than the predicate. We are making no claim of better performance only equivalence.

Biocompatibility –
The subject device has no patient contact. Therefore ISO 10993 testing is not required.
Discussion – The Praxis CytoCore has no patient contact, therefore, we did not perform biocompatibility.

Electrical Safety and EMC
Electrical safety and EMC testing were conducted on the subject device. The system complies with AAMI ANSI ES 60601-1: 2005 + A1: 2012 and IEC 60601-2-22 Edition 3.1 2012-10 standards for safety and IEC 60601-1-2: 2014 for EMC.

VIII Discussion of Differences and Conclusion

Discussion of Differences –
The primary difference between the Praxis CytoCore and – K972496 – TAO Aspirator and Plastic Finger is the use of a battery to run a DC motor in the subject device. The use of both the subject and predicate device is the similar in that they both collect tissue materials. The subject device uses a DC motor which rotates the user suppled needle in an alternating clockwise /

counterclockwise rotation to assist in collecting tissue samples vs. that of the predicate which is an in/out motion. An evaluation of risk and testing for safety and effectiveness demonstrated that this difference was not significant. Performance testing shows that when compared to the predicate device, CytoCore was equivalent.

Substantial Equivalence Conclusion

The performance testing has demonstrated that the subject devise met the applicable standard performance requirements. The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.