February 27, 2020

AprioMed AB
Katrin Svensson
Director, Quality and Regulatory Affairs
Virdings Alle 28
Uppsala, Sweden 754 50

Re: K193268
Trade/Device Name: APrioCore plus
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: January 20, 2020
Received: January 22, 2020

Dear Katrin Svensson:

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)*
K193268

Device Name
AprioCore plus

Indications for Use *(Describe)*
AprioCore plus is intended for use in obtaining core biopsy specimens from soft tissue such as breast, kidney, liver, lung, thyroid, lymph nodes and various soft tissue masses performed under image guidance techniques for soft tissue biopsy.

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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5 510(K) SUMMARY

As Required by 21 CFR 807.92(c) 510(k) Summary

5.1 Submitter/510(k) Holder

AprioMed AB
Virdings Allé 28
Uppsala, SWEDEN 754 50

Contact Person: Katrin Svensson, Director Quality & Regulatory Affairs
Telephone: +46 (0) 73- 345 14 40

Date Prepared: November 22, 2019

5.2 Device

Proprietary Name:	AprioCore plus
Common/Usual Names:	Instrument, Biopsy
Classification Names:	Instrument, Biopsy
Regulation number:	876.1075, Gastroenterology-Urology Biopsy Instrument
Product Code:	KNW
510(k) number:	TBD

5.3 Predicate Devices identification

Proprietary Name:	Quick-Core Biopsy Needle
Common/Usual Names:	Instrument, Biopsy
Classification Names:	Instrument, Biopsy
Regulation number:	876.1075, Gastroenterology-Urology Biopsy Instrument
Product Code:	KNW
510(k) number:	K973565

5.4 Device Description

AprioCore plus is a manually operated, sterile, single use, semi-automatic, spring-loaded biopsy needle. AprioCore plus is provided in a variety of sizes (gauge and length) and is compatible with AprioMed devices Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle.

5.5 Technological Characteristics

AprioCore plus is a spring-loaded semi-automatic biopsy needle that is visible in CT (computed tomography) and fluoroscopy. The device is equipped with a beveled needle with centimeter markings and an echogenic distal tip for visualization during ultrasound imaging.

During use, the position of the device is monitored using imaging technique. The inner stylet is equipped with a slot (specimen notch) to collect a biopsy specimen. Compared to predicate device, AprioCore plus has a shorter tip, thereby making it possible to take a biopsy specimen closer to nearby sensitive anatomy/structure. The housing of the device has been designed to facilitate different hand positioning options during use.

The materials used for construction of AprioCore plus needles are typical for this type of medical device. The only material in direct patient contact is the stainless steel AISI 304 and stainless steel AISI 302.

5.6 Indications for Use

AprioCore plus is intended for use in obtaining core biopsy specimens from soft tissue such as breast, kidney, liver, lung, thyroid, lymph nodes and various soft tissue masses performed under image guidance techniques for soft tissue biopsy.

5.7 Substantial Equivalence

AprioMed AB has determined that AprioCore plus are substantially equivalent to the predicate device based on the indications for use, compliance with internationally recognized design and performance standards, material specifications, use environments, and performance. The differences between subject devices and the predicate device used for the same indications for use do not raise new issues of safety and effectiveness.

A substantial equivalence comparison table of subject devices, AprioCore plus and the predicate device, Quick-Core Biopsy Needle (K973565) is provided in Table 5-1.

Table 5-1: Substantial equivalence table

Parameter	Subject Devices	Predicate Device
Proprietary Name	AprioCore plus	Quick-Core Biopsy Needle
510(k)	This 510(k) application	K973565
Device Classification Name	Biopsy needle	Biopsy needle
Product Code	KNW	KNW
Regulation description	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument
Regulation Number	21 CFR 876.1075	21 CFR 876.1075
Intended/use Indications for Use	AprioCore plus is intended for use in obtaining core biopsy specimens from soft tissue such as breast, kidney, liver, lung, thyroid, lymph nodes and various soft tissue masses performed under image guidance techniques for soft tissue biopsy.	Quick-Core Biopsy Needles are intended for soft tissue biopsy. The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard technique for soft tissue biopsy should be employed.
Anatomical sites	Specimens from soft tissue such as breast, kidney, liver, lung, thyroid, lymph nodes and various soft tissue masses	Soft tissue biopsy
Device type	Semi-automatic biopsy gun, spring-operated	Semi-automatic biopsy gun, spring-operated
Visualization technique	Conventional imaging guidance equipment excluding MRI	Conventional imaging guidance equipment excluding MRI
Single Use	Yes	Yes
Sterile	Yes, Ethylene Oxide	Yes, Ethylene Oxide
Needle material	Stainless Steel	Stainless Steel
Needle diameter (Gauge)	16G and 18G	14G, 16G, 18G and 20G
Needle length	8.5, 9.5, 13.5, 14.5, 18.5 and 19.5 cm	6, 9, 15 and 20 cm
Specimen notch size	10 mm and 20 mm	10 mm and 20 mm

5.7.1 Indication for Use

AprioMed has determined that the intended use of AprioCore plus are substantially equivalent to the predicate device.

5.7.2 Materials

AprioCore plus and the predicate device is constructed with medical grade stainless steel and the needle material fulfill the, by FDA, recognized consensus standard, ISO 9626 Stainless Steel Needle Tubing for the Manufacture of Medical Devices. AprioMed has concluded that the subject device is substantial equivalent to the predicate device.

5.7.3 Use Environment

AprioCore plus and the predicate device are used in the same clinical setting using conventional imaging guidance equipment excluding MRI. The users are physicians trained in percutaneous image-guided biopsy sampling of soft tissue. AprioMed has concluded that the subject device is substantial equivalent to the predicate device.

5.7.4 Size

AprioCore plus needle gauge size fulfill the, by FDA, recognized consensus standard, ISO 9626 Stainless Steel Needle Tubing for the Manufacture of Medical Devices. AprioMed has determined that the gauge, length and specimen notch size of AprioCore plus is substantially equivalent to the predicate device.

5.7.5 Activation force

Subject and predicate device was tested side-by-side to compare activation force. The activation force shall be equivalent or higher compared to the predicate device to prevent accidentally activation. AprioMed concluded that the subject device is substantial equivalent to the predicate device.

5.7.6 Penetration force

Subject and predicate device was tested side-by-side to compare penetration force. AprioCore plus shall have a penetration force that is equal or lower than corresponding penetration force of the predicate device, in order to cut through tissue easily. AprioMed concluded that the subject device is substantial equivalent to the predicate device.

5.7.7 Specimen size

Subject and predicate device was tested side-by-side to compare specimen extraction size by weight. AprioMed concluded that the subject device is substantial equivalent to the predicate device.

5.8 Summary of non-clinical and performance testing

Bench testing was performed to evaluate the performance and functionality of the subject device against requirement specification. The subject device has been subjected to compliance testing according to, by FDA, recognized consensus standards ISO 9626, ISO 10993-7, ISO 10993-1, ISO 11607-1. Results from testing performed confirms that the design requirement specification and user needs have been met. The subject device is confirmed to be safe and effective for the intended use.

5.8.1 Sterilization and shelf life

AprioCore plus is delivered sterile and have successfully been tested according to ISO 11607-1. The label shelf life is 3 years.

5.8.2 Biocompatibility testing

AprioCore plus has successfully been tested for cytotoxicity, sensitization, intracutaneously irritation, acute systemic toxicity and material medicated pyrogenicity. The test results verify that the biocompatibility criteria given in ISO 10993 are fulfilled. AprioMed concludes that AprioCore plus is non-toxic and biocompatible.

5.8.3 Performance testing – Bench

The performance of AprioCore plus has been verified. Tests as described in table 5-2 have been completed.

Table 5-2: Performance testing summary

Test:	Description:
Depth projection	To confirm that subject device will not extend over the stylet tip (over-throw) during use. Conformity has been demonstrated.
Penetration force	To confirm that the penetration force of the subject device is equivalent to predicate device. Conformity has been demonstrated.
Loading force	To confirm that the loading force of the subject device is equivalent to predicate device and that the user is able to load the subject device (force required to compress the spring). Conformity has been demonstrated.
Activation force	To confirm that the force to activate the subject device (release the spring) is not too low, resulting in unintentional activation during use. Conformity has been demonstrated.
Mechanical durability	To confirm that subject device withstands the forces applied to the subject device during normal use. Conformity has been demonstrated.
Tissue sample extraction test	To confirm that the subject device can successfully retrieve biopsy specimen multiple times. Conformity has been demonstrated.
Tip configuration	To confirm that it is possible to take a biopsy specimen closer to nearby sensitive anatomy/structure compared to predicate device. Subject device shall have a tip dead-space that is shorter compared to predicate device. Conformity has been demonstrated.
Visibility	To confirm that the invasive part of subject device is visible in CT, Fluoroscopy and Ultrasound. Conformity has been demonstrated.
Compatibility	To confirm that the device is compatible with coaxial needle standardized sizes as per ISO 9626 has been applied. AprioCore plus has been demonstrated to be compatible with AprioMed Gangi-SoftGuard and Gangi-HydroGuard.
Qualification metal tubing/needle component	The stainless-steel tubing fulfills the requirement in ISO 9626 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods. Conformity has been demonstrated.

5.9 Summary and Conclusion

Conclusion drawn from testing completed is that AprioCore plus is equivalent to the predicate. AprioCore plus is as safe, as effective, and performs as well as or better than the predicate device.