December 18, 2018

AprioMed AB
Katrin Svensson
Director Quality & Regulatory Affairs
Virdings Allé 28
Uppsala, 75450
Sweden

Re: K181756
Trade/Device Name: Gangi-SoftGuard Coaxial Needle
Gangi-HydroGuard Coaxial Needle
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: November 12, 2018
Received: November 16, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K181756

Device Name
Gangi-SoftGuard Coaxial Needle
Gangi-HydroGuard Coaxial Needle

Indications for Use (Describe)
As a guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, spleen, lymph nodes and various soft tissue lesions.

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: December 12, 2018

5.2 Device
Proprietary Name: Gangi-SoftGuard Coaxial Needle
Gangi-HydroGuard Coaxial Needle
Common/Usual Names: Biopsy Needle
Regulation number: 21 CFR 876.1075
Classification Name: Gastroenterology-Urology Biopsy Instrument
Class: II
Product Code: FCG
510(k) number: K181756

5.3 Predicate Devices and Reference Device identification
Predicate device:
Proprietary Name: Bard TruGuide Disposable Coaxial Biopsy Needle
Common/Usual Names: Biopsy Needle
Regulation number: 21 CFR 876.1075
Classification Name: Gastroenterology-Urology Biopsy Instrument
Class: II
510(k) number: K936194
Product Code: FCG

Reference device:
Proprietary Name: Surgineedle™ Pneumoperitoneum Needle
Common/Usual Names: Pneumoperitoneum Needle
Regulation number: 21 CFR 876.1500
Classification Name: Endoscope and accessories
Class: II
510(k) number: K863330
Product Code: FHO
5.4 Device Description

Gangi-SoftGuard Coaxial Needle together with Gangi-HydroGuard Coaxial Needle forms the Gangi Coaxial Needle family. Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle are manually operated, sterile, single use coaxial guiding needles with a spring loaded blunt-tip stylet, to be used as a guiding needle for biopsy instruments in procedures in soft tissue. Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle has the same intended use.

Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle are gastroenterological, manually operated, sterile, single use coaxial introducer needles. Both Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle consists of three parts: a needle (cannula) provided with a trocar stylet, and a spring-loaded blunt tip stylet. The difference from Gangi-SoftGuard Coaxial Needle is that Gangi-HydroGuard Coaxial Needle has a Luer hub located on the blunt stylet housing and the blunt stylet is hollow and has a distal tip hole. This enables injection of fluid without the need to remove the blunt stylet.

5.5 Technological Characteristics

Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle are delivered with the trocar stylet inserted in the needle (cannula). When the trocar is exchanged to the blunt stylet, the blunt tip protrudes out from the distal end of the needle (cannula) which makes the coaxial needle tip non-traumatic, shielding the surroundings from the sharp needle (cannula tip).

The position of the coaxial needle is monitored using imaging technique. If resistance or hard surface is met when using the device, the blunt tip retracts into the needle (cannula), exposing the sharp needle (cannula) tip and enabling cutting through tissue. The retraction of the blunt tip can be prevented by pressing the proximal part of the stylet (covered by a plastic cap) or the proximal Luer hub on the housing.

After cutting through the tissue with the sharp needle (cannula) and the resistance is reduced, the hollow blunt stylet tip springs back i.e., the non-traumatic tip will once again shield the surrounding tissue from the sharp needle (cannula tip).

When the targeted lesion has been reached, Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle enables biopsy to be performed per normal hospital routines.

The materials used for construction of the needles are typical for this type of medical device. The only material in direct patient contact is stainless steel AISI 304 and stainless steel AISI 302. The needles are designed in accordance with ISO 7864 - Sterile hypodermic needles for single use.
5.6 **Indications for Use**
Gangi-SoftGuard Coaxial Needle is intended as a guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, spleen, lymph nodes and various soft tissue lesions.

Gangi-HydroGuard Coaxial Needle is intended as a guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, spleen, lymph nodes and various soft tissue lesions.

5.7 **Substantial Equivalence**
AprioMed AB has determined that Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle 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, Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle and the predicate device, Bard TruGuide Disposable Coaxial Biopsy Needle (K936194) is provided in Table 5-1.
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Subject Devices</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary Name</td>
<td>Gangi-SoftGuard Coaxial Needle</td>
<td>Bard TruGuide Disposable Coaxial Biopsy Needle</td>
</tr>
<tr>
<td></td>
<td>Gangi-HydroGuard Coaxial Needle</td>
<td></td>
</tr>
<tr>
<td>510(k)</td>
<td>This 510(k) application</td>
<td>K936194</td>
</tr>
<tr>
<td>Device Classification Name</td>
<td>Biopsy needle</td>
<td>Biopsy needle</td>
</tr>
<tr>
<td>Product Code</td>
<td>FCG</td>
<td>FCG</td>
</tr>
<tr>
<td>Regulation description</td>
<td>Gastroenterology-Urology Biopsy Instruments</td>
<td>Gastroenterology-Urology Biopsy Instruments</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>21 CFR 876.1075</td>
<td>21 CFR 876.1075</td>
</tr>
<tr>
<td>Intended Use/Indications for Use</td>
<td>As a guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, spleen, lymph nodes and various soft tissue lesions.</td>
<td>The Coaxial biopsy needle guide is intended for use as a guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, spleen, lymph nodes and various soft tissue lesions.</td>
</tr>
<tr>
<td>Device type</td>
<td>Coaxial introducer needle with a spring loaded blunt tip stylet/hollow blunt tip stylet</td>
<td>Coaxial introducer needle with a blunt tip stylet</td>
</tr>
<tr>
<td>Visualization technique</td>
<td>Conventional imaging guidance equipment excluding MRI</td>
<td>Conventional imaging guidance equipment excluding MRI</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sterile</td>
<td>Yes, Ethylene Oxide</td>
<td>Yes, Ethylene Oxide</td>
</tr>
<tr>
<td>Needle material</td>
<td>Stainless Steel</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Needle Hub</td>
<td>Luer</td>
<td>Luer</td>
</tr>
<tr>
<td>Needle size</td>
<td>12G-17G</td>
<td>11G-19G</td>
</tr>
<tr>
<td></td>
<td>7.1-17.1 cm</td>
<td>7.0-17.8 cm</td>
</tr>
<tr>
<td></td>
<td>15G-17G</td>
<td>12.1-17.1 cm</td>
</tr>
<tr>
<td>Needle penetration depth</td>
<td>17.1 cm free length</td>
<td>17.8 cm free length</td>
</tr>
<tr>
<td>Anatomical sites</td>
<td>Liver, kidney, spleen, lymph nodes and various soft tissue lesions</td>
<td>Liver, kidney, spleen lymph nodes and various soft tissue lesions</td>
</tr>
</tbody>
</table>
5.7.1 Intended Use/Indication for Use
AprioMed has determined that the intended use of Gangi-HydroGuard and Gangi-SoftGuard coaxial biopsy needle are substantially equivalent to the predicate device.

5.7.2 Materials
AprioMed has determined that the Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle are substantially equivalent to the predicate device based on materials. Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle and the predicate is constructed with medical grade stainless steel. Gangi Coaxial Needle material also fulfill the, by FDA, recognized consensus standard, ISO 9626 Stainless Steel Needle Tubing for the Manufacture of Medical Devices.

5.7.3 Use Environment
Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle is intended to be used in a standard clinical setting for percutaneous imaging-guided biopsy sampling excluding in Magnetic Resonance Imaging (MRI) equipment. The users are physicians trained in percutaneous image-guided biopsy sampling of soft tissue. AprioMed has determined that Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle are substantially equivalent to the predicate device based on the use environment.

5.7.4 Size, stylet size and penetration depth
AprioMed has determined that the sizes, stylet size and penetration depth of Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle is substantially equivalent to the predicate device.

5.7.5 Tip design
AprioMed has determined that the tip design of Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle is substantially equivalent to the predicate device.

5.7.6 Penetration force
AprioMed has determined that Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle are substantially equivalent to the predicate device with respect to needle penetration.

5.7.7 Safety Features
AprioMed believes that Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle is substantially equivalent to the predicate device in respect to safety features. Neither Gangi-SoftGuard Coaxial Needle, Gangi-HydroGuard Coaxial Needle nor the predicate has any specific safety features.

5.8 Summary of non-clinical and performance testing
Testing in the form of bench testing was performed to evaluate the performance and functionality to evaluate the device against requirements specification. The devices have been subjected to compliance testing to voluntary standards e.g. ISO 7864, ISO 9626, ISO 10993-7, ISO 10993-1, ISO 11607-1.

Results from verification and validation testing demonstrates that conformance to applicable technical requirements specification and user needs have been met and substantial equivalence has been demonstrated.
5.8.1 Biocompatibility testing
The material used in Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle has been tested for biocompatibility in accordance with ISO 10993 for externally communicating devices in contact with tissue for 24 hours or less. The material in direct patient contact is the cannula needle and stylets made of stainless steel AISI 304 and stainless steel AISI 302. Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle have successfully been tested for:
- Cytotoxicity
- Sensitization
- Intracutaneously irritation
- Acute Systemic Toxicity
- Pyrogenicity

The test results verify that the biocompatibility criteria given in ISO 10993 are fulfilled. AprioMed concludes that Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle is non-toxic and biocompatible.

5.8.2 Performance testing – Bench
5.8.2.1 Qualification metal tubing
The stainless-steel tubing is qualified in compliance with ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods, and conformity demonstrated.

5.8.2.2 Qualification of Needle component
The needle used for Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle are qualified in compliance with ISO7864:2016 Sterile hypodermic needles for single use – Requirements and test methods.

5.8.2.3 Conical Fittings
The Luer lock fittings used for Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle are qualified in compliance with ISO 594 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment, and conformity demonstrated.

5.8.2.4 Mechanical performance
The mechanical performance testing of Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle has passed all design requirements.

5.8.2.5 Verification of penetration force and spring
The penetration force and the spring force have been evaluated and passed all design requirements.

5.9 Summary and Conclusion
Based on the above discussion, the non-clinical testing supports the safety of the device and demonstrates that the Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle should perform as intended in the specified use conditions. The data supports the substantial equivalence determination between the Gangi-SoftGuard Coaxial Needle and Gangi-HydroGuard Coaxial Needle and the predicate device.