August 28, 2023

Limaca Medical Ltd
% Susan Alpert
Regulatory Affairs Consultant
SFADC LLC
2425 L Street NW, Apt 307
Washington, District of Columbia 20037

Re: K231422
Trade/Device Name: Precision GI
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Received: July 27, 2023

Dear Susan Alpert:

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,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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.

Submission Number *(if known)*

K231422

Device Name

Precision GI

Indications for Use *(Describe)*

Precision GI is used with an ultrasound endoscope for fine needle biopsy (FNB) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.

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

Limaca's Precision GI

Submitter:	**Limaca Medical ltd.**
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Phone: e-mail:	972-4-6135050 info@limaca-medical.com
Contact Person:	Assaf Klein
Date Prepared:	27 July 2023

Name of Device:	Precision GI
Common or Usual Name:	Fine needle biopsy
Classification Name:	Kit, Needle, biopsy
Regulatory Class:	21 CFR 876.1075, class II
Product Code:	FCG
Primary Predicate Device:	EndoDrill® Model X biopsy instrument by Bibbinstruments AB (K212423)
Reference Device:	EchoTip ProCore HD Ultrasound Biopsy Needle Fine needle biopsy system, by Cook Medical (K210476)

Device Description

The Precision GI Endoscopic ultrasound-guided Fine Needle Biopsy (EUS-FNB) device is a motorized, automated, rotational, cutting EUS-Biopsy needle with an echogenic tip inserted and operated through the instrument channel of an ultrasound imaging endoscope.

The Limaca Precision GI FNB needle is available in one size - 20G.

The Precision GI Endoscopic ultrasound-guided Fine Needle Biopsy (EUS-FNB) device is a battery-operated, motorized, automated rotational cutting biopsy device with an echogenic needle tip, advanced and operated by the physician through the accessory instrument channel of an ultrasound imaging endoscope.

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Intended Use / Indications for Use

The Precision-GI device is intended for use with an ultrasound endoscope (EUS) for fine needle biopsy (FNB) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.

Comparison of the Technological Characteristic with the Predicate Device

Precision GI is substantially equivalent to other legally marketed biopsy systems including the predicate: EndoDrill® Model X biopsy instrument by Bibbinstruments AB (k212423)

The Precision GI has the same intended use as its predicate and is used on the same anatomical sites.

The Precision GI device, like its predicate, the EndoDrill® Model X biopsy instrument by Bibbinstruments AB (k212423), is used in conjunction with an ultrasound endoscope for fine needle biopsy (FNB). Both devices perform tissue acquisition while rotating and advancing electrically. Both the Precision GI device and its predicate use a motor for rotation.

The motor rotation speed of the Precision GI device is 800RPM, while the motor speed of its predicate is higher. The reduced motor speed is safe and yet provides a good sample acquisition as demonstrated in bench tests and preclinical study.

Both devices have an echogenic pattern at the distal end of the needle to allow visualization of the needle tip under endoscopic ultrasound. The Precision GI device, like its predicate, EndoDrill® Model X biopsy instrument by Bibbinstruments AB (k212423), consists of needle cannula, stylet, sheath and handle.

The needle geometry of the Precision GI and its predicate is similar. Both have flat circumferential sharpening, however the Precision GI sharpening is internal and the predicate is external. The Precision GI device needle size is 20GA and is made of Nitinol with PTFE coating, while its predicate size is 17GA needle made of Stainless steel. However, there are other FNB needles of different sizes and material, similar to the Precision GI that have been previously approved, such as EchoTip ProCore HD Ultrasound Biopsy Needle Fine needle biopsy system, by Cook Medical (K210476) (Reference device).

Performance Data

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The Precision GI device is determined to be substantial equivalent to the predicate device. Engineering bench testing as well as pre clinical study have been performed to support substantial equivalence with the predicate device. Various bench tests as well as pre- clinical data were included in the performance data, including: Dimensional Attributes and EUS compatibility, Shaft insertion/withdrawal force, Stopper lock operation force, Sample Acquisition, Echogenicity, Needle Deformation, Packaging Endurance to Distribution Environmental Hazards, Handle resistance force, Extender friction torque, Stylet withdrawal force, Stylet hold-in- position force, Sheath bonding strength, Axial stoper strength, Stylet bonding strength, Handle bending torque durability, Needle bonding torque strength, Tissue wrapping, Needle cyclic loading durability, Needle bonding cyclic loading durability, Needle tissue Penetration force, Needle bonding tensile strength, biocompatibility and sterilization.

Conclusions

The Precision GI is as safe and effective as the EndoDrill® Model X biopsy instrument by Bibbinstruments AB (k212423). The Precision GI has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the Precision GI and its predicate and reference devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Precision GI is as safe and effective as the EndoDrill® Model X biopsy instrument by Bibbinstruments AB (k212423). Thus, the Precision GI is substantially equivalent to the predicate device.