April 23, 2024

Laborie Medical Technologies Corp.
Arpit Sisodiya
Sr. Regulatory Affairs Specialist
180 International Drive
Portsmouth, New Hampshire 03801

Re: K234107
Trade/Device Name: Solar™ Anorectal Manometry Catheter (Model Number: K1210AC-L-2212)
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: KLA
Dated: March 21, 2024
Received: March 21, 2024

Dear Arpit Sisodiya:

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,

Anthony Lee -S

Anthony C. Lee, Ph.D., M.B.A.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234107

Device Name

Solar™ Anorectal Manometry Catheter (Model Number: K1210AC-L-2212)

Indications for Use *(Describe)*

The Solar anorectal manometry catheter is a non-sterile, single patient use catheter for use on patient requiring anorectal manometry testing.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Laborie

510(k) Summary

Applicant: Laborie Medical Technologies Corp.
180 International Drive,
Portsmouth, NH 03801

Contact Person: Arpit Sisodiya
Sr. Regulatory Affairs Specialist
Phone: (313) 420-8956
Email: asisodiya@laborie.com

Device Name

Device Trade Name: Solar™ Anorectal Manometry Catheter (K1210AC-L-2212)
Common Name: Monitor, Anorectal Motility, And Tube
Classification Name: Gastrointestinal Motility Monitoring System
Regulation Number: 21 CFR 876.1725
Product Code: KLA
Device Classification: Class II

Legally Marketed Predicate Device

Predicate 510(k) Number: K022023
Predicate Trade Name: Latitude Anorectal Pressure Catheter (Model: GIM-6000A)
Product Code: KLA

Device Description Summary

The Solar™ Anorectal Manometry Catheter is a high-resolution anorectal manometry (HRAM) catheter. It is a diagnostic device used to assess the function of anal and rectum muscles. The device consists of 10 air-charged sensing balloons which can sense pressures during anorectal manometry, along with a distal balloon used for the assessment of recto anal inhibitory reflex (RAIR). The catheter is disposable and non-sterile. Through manual insertion in the rectum, the device assesses pressures within the anorectal anatomy as well as assessing sensation and reflexes.

This product is non-sterile, single patient use catheter intended for use with a reusable Solar™ Anorectal Manometry Charger on patients requiring lower gastrointestinal pressure measurements.

Intended Use/Indications for Use

The Solar anorectal manometry catheter is a non-sterile, single patient use catheter for use on patient requiring anorectal manometry testing.

Indications for Use Comparison

The indications for use of the subject device (Solar™ Anorectal Manometry Catheter) and the predicate device (Latitude anorectal pressure catheter) are the same. The Solar™ Anorectal Manometry Catheter is indicated for use on patient

requiring anorectal manometry testing. Similarly, the predicate, Latitude anorectal pressure catheter (GIM-6000A) is indicated for use in anorectal pressure studies.

Technological Comparison

The basic technology for the subject device (Solar™ Anorectal Manometry Catheter) and the predicate device (Latitude anorectal pressure catheter) is the same. There are 10 sensing balloons and one rectal balloon on the Solar™ Anorectal Manometry Catheter, whereas the Latitude anorectal pressure catheter has 4 sensing balloons and one rectal balloon. Both the Solar™ Anorectal Manometry Catheters and Latitude anorectal pressure catheters connect to ancillary pressure measurement systems (charger) that use a piston-and-cylinder charging mechanism to inject a small amount of air into the sensing balloons and internal transducers to read the pressure. The Latitude catheter uses individual charging cables for each sensing balloon while the Solar™ Anorectal Manometry Charger has a single catheter connection and charges all 10 balloons simultaneously.

Non-Clinical and/or Clinical Tests Summary and Conclusions

A series of nonclinical bench performance testing was conducted on the Solar™ Anorectal Manometry Catheter and Solar™ Anorectal Manometry charger to demonstrate Substantial Equivalence.
Following tests were performed on Solar™ Anorectal Manometry Catheter to demonstrate the Substantial Equivalence:

- Design Verification testing (visual, dimensional, performance/ functional, destructive) after 6 Months Accelerated Aging
- Design Verification testing (visual, dimensional, performance/ functional, destructive) after transit simulation
- Biocompatibility (Cytotoxicity, irritation, sensitization)
- Bioburden

Following tests were performed on Solar™ Anorectal Manometry Charger:

- Functionality Testing
- Biological Safety Assessment
- Distribution Testing
- Firmware Testing (Compatibility with the Solar GI system)

Additionally, a formative evaluation was conducted to assess the usability of the device by applying evaluation process specified in EN IEC 62366-1, Medical devices-Part 1: Application of usability engineering to medical devices.

Conclusion

Performance testing was conducted on all key performance attributes of the device. All samples met their acceptance criteria, demonstrating that when manufactured to specification, the device functions as intended and can be found substantially equivalent to the predicate device.