May 6, 2024

Laborie Medical Technologies Corp.
Ingrid Dirtzu
Regulatory Affairs Specialist II
180 International Drive
Portsmouth, New Hampshire 03801

Re: K240007
Trade/Device Name: Solar Compact (G4-1)
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: FFX
Dated: April 5, 2024
Received: April 5, 2024

Dear Ingrid Dirtzu:

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,

Shanil P. Haugen -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240007

Device Name

Solar Compact (G4-1)

Indications for Use *(Describe)*

The Solar Compact is intended to record, store, view, and analyze pressure, impedance, and EMG data, gathered from anywhere in the gastrointestinal tract (pharynx, esophagus, stomach, and anorectal area, including rectum and pelvic floor) to assist in the diagnosis and evaluation of gastrointestinal and swallowing disorders. Designated catheters and accessories are required for measurement in each specific area of the gastrointestinal tract.

An optional perfusion pump can also be used for automated balloon filling (for anorectal manometry studies). The filling lumen of the catheter can be connected to the perfusion pump.

The Solar Compact is indicated for use in adult to infants with common gastrointestinal conditions, for the monitoring and diagnosis of motility disorders of the GI 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.

510(k) #: K240007

510(k) Summary

Prepared on: 2024-04-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Laborie Medical Technologies Corp.
Applicant Address	180 International Drive Portsmouth NH 03801 United States
Applicant Contact Telephone	952-564-3948
Applicant Contact	Ms. Ingrid Dirtzu
Applicant Contact Email	idirtzu@laborie.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Solar Compact (G4-1)
Common Name	Gastrointestinal motility monitoring system
Classification Name	System, Gastrointestinal Motility (Electrical)
Regulation Number	876.1725
Product Code	FFX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K052338	Solar GI with CIM-AUX	FFX
K121014	MPP Plus	FFX

Device Description Summary

21 CFR 807.92(a)(4)

The Solar Compact is a medical device for measuring gastrointestinal motility characteristics. The system consists of an electromechanical hardware device which connects to pressure catheters (air-charged or solid-state), and a PC software. Catheters provide measurements of pressure and impedance to the device from various sites along the gastrointestinal tract, which are then displayed and analyzed by the Laborie PC software. This provides the clinician with data that may aid in the diagnosis or management of various gastrointestinal disorders. Additionally, the system connects to surface electrodes to provide EMG measurements of the muscles along the pelvic floor. Devices such as pressure catheters and surface electrodes are required to complete a gastrointestinal motility investigation, but they are not considered part of the Solar Compact device and not included standard with the system.

The device hardware consists of an external housing, pneumatics to inflate and deflate rectal balloons, and electronics to readout data from the pressure catheters and to control all other functions of the system. The device connects to a PC via Bluetooth to display measurements `within the Laborie software. The Laborie software contains a patient database module, an investigation module, and an analysis module. The software displays measurements from the system as time-tracing based plots, Clouse Countour Plots (High Resolution Manometry), and as 3D plots. Clinicians can analyze the data provided by placing markers and using calculations within the software. The device does not provide an independent diagnosis.

The Solar Compact device is compatible with a number of of catheters for these aforementioned parameter measurements. For a full list of these compatible catheters please consult the instructions for use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Solar Compact is intended to record, store, view, and analyze pressure, impedance, and EMG data, gathered from anywhere in the gastrointestinal tract (pharynx, esophagus, stomach, and anorectal area, including rectum and pelvic floor) to assist in the diagnosis and evaluation of gastrointestinal and swallowing disorders. Designated catheters and accessories are required for measurement in each specific area of the gastrointestinal tract.

An optional perfusion pump can also be used for automated balloon filling (for anorectal manometry studies). The filling lumen of the catheter can be connected to the perfusion pump.

The Solar Compact is indicated for use in adult to infants with common gastrointestinal conditions, for the monitoring and diagnosis of motility disorders of the GI tract.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the proposed Solar Compact are similar to that of the primary predicate device, Solar GI with CIM-AUX (K052338). While the number of sites for investigation by way of example has been limited, the Solar Compact device retains the statement that it can be used to analyze data anywhere in the gastrointestinal tract, and in this regard the devices are similar.

The signals analyzed by the proposed Solar Compact are limited relative to the Solar GI with CIM-AUX and do not specify swallow or respiration. The proposed Solar Compact specifies impedance data within the indications as a form of auxiliary device input data which the system analyzes. However, the predicate device, Solar GI with CIM-AUX, has incorporated impedance measurement since the Solar GI with CIM-AUX (K052338) clearance.

The MPP Plus (K121014) is an accessory to a system whose primary intended use is as an accessory to a complete gastrointestinal motility system, whereas the proposed Solar Compact is a complete gastrointestinal motility system. The proposed Solar Compact incorporates the same functionality of automated balloon filling that specified for the predicate MPP Plus (K121014), in order to achieve the system's intended use of gastrointestinal motility investigations.

Technological Comparison 21 CFR 807.92(a)(6)

The principles of operation, energy source, measuring range, and materials used in the proposed Solar Compact are similar to those used in the predicate devices.

The proposed Solar Compact features a smaller device form factor relative to primary predicate Solar GI with CIM-AUX (K052338). Additionally, Bluetooth functionality is incorporated directly within the main housing of the device, rather than as an accessory module.

For the proposed Solar Compact, the pump is incorporated within the body of the device, rather than as an accessory item as on the MPP Plus predicate (K121014). The pump system in the proposed Solar Compact is an air compressor and does not perfuse water, whereas the pump in the MPP Plus pressurizes a water-perfusion system for compatibility with water-perfused catheters.

The proposed Solar Compact is compatible with solid-state and air-charged catheters, which is identical to the primary predicate, Solar GI with CIM-AUX (K052338). The Solar GI with MPP Plus (K121014) is compatible with water catheters only; the Solar GI with MPP Plus is a secondary predicate and is considered not applicable in this regard.

The pump in the proposed Solar Compact is able to control both inflation and deflation, whereas the pump in the predicate MPP Plus (K121014) controls inflation only and does not have a controlled deflation.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

System verifications were conducted, including functional, mechanical, electrical, lifetime verification testing, calibration and volume measurement, to ensure that the Solar Compact demonstrates substantial equivalence by meeting requirements defined for the device. Additionally, software verifications were conducted to verify system requirements during device development and an additional software verification was performed to confirm updates integrating the Solar Compact software into the Laborie software 10.1 release. Package integrity testing was performed to the ISTA 3A standard and electrical/mechanical safety testing was performed to demonstrate compliance with IEC 60601-1 and 60601-1-2.

Clinical testing was not conducted and is not applicable for demonstrating substantial equivalence.

The Solar Compact device passed all verification testing, confirming the device performance and demonstrating that the device is as safe, as effective, and perform as as well or better than the legally marketed device predicates.