November 22, 2023

Fogg System Company, Inc.
Jared Walkenhorst
Novare Medical Consulting LLC.
1765 Dusty Boot Dr
Lafayette, Colorado 80026

Re: K222712
Trade/Device Name: Fogg System Patient Monitoring Cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: September 8, 2022
Received: September 8, 2022

Dear Jared Walkenhorst:

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,

Jennifer W. Shih -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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.

510(k) Number *(if known)*
K222712

Device Name
Fogg System Patient Monitoring Cables

Indications for Use *(Describe)*
The Patient Monitoring Cables are intended to be used with SpO2, Temperature, BP, ECG, Cardiac Output, and related monitoring devices. The Patient Monitoring Cables are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device, or between monitoring devices, for general monitoring and/or diagnostic evaluation by health care professionals.

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) SUMMARY

Submitter's Name:	Fogg System Company, Inc.
Submitter's Address:	15592 East Batavia Drive Aurora, CO 80011 United States
Contact Person:	Jared Walkenhorst Novare Medical Consulting 720.215.9244 novaremedllc@gmail.com
Date Summary was Prepared:	16 Nov 2023
Trade or Proprietary Name:	Fogg System Patient Monitoring Cables
Common or Usual Name:	Patient transducer and electrode cable (including connector)
Classification:	Class II per 21 CFR §870.2900
Product Code:	DSA

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Patient Monitoring Cables are replacements for similar accessory cables manufactured or specified by Original Equipment Manufacturers (OEM) for their respective transducers, monitors, and peripheral equipment. These are non-patient-contact, insulated, electrical cables with a connector (plug or receptacle) at each end, designed to transmit electrical power and/or signal (data) between medical devices (e.g., to connect SpO2 sensor, IBP transducer to a patient monitor). They are not intended to connect to the mains (i.e., not mains power cables), do not generate any type of power and/or signal, and have no additional non-electrical conducting or processing functionality.

INDICATIONS FOR USE

The Patient Monitoring Cables are intended to be used with SpO2, Temperature, BP, ECG, Cardiac Output, and related monitoring devices. The Patient Monitoring Cables are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device, or between monitoring devices, for general monitoring and/or diagnostic evaluation by health care professionals.

TECHNOLOGICAL CHARACTERISTICS

The Fogg System Patient Monitoring Cables are identical in intended use and similar in basic shape, material, and performance characteristics to the predicate device. There are no differences in the fundamental scientific technology shared by both the subject and predicate devices.

Table 1 Substantial Equivalence Table

Description	**Subject Device**	**Predicate Device (K203635)**
Device Name	Patient Monitoring Cables	Patient Monitoring Cables
Indications for Use	The Patient Monitoring Cables are intended to be used with SpO2, Temperature, BP, ECG, Cardiac Output, and related monitoring devices. The	The Patient Monitoring Cables are intended to be used with ECG, EKG, Spo2 and BP monitoring devices. The Patient Monitoring Cables are used to connect

	Patient Monitoring Cables are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device, or between monitoring devices, for general monitoring and/or diagnostic evaluation by health care professionals.	electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by health care professional.
Design/ Appearance	Cables with various connectors (please see the table below)	Cables with various connectors
Length	Various specified standard lengths (please see the table below)	Various specified standard lengths
Material	Tin copper, PVC, Santoprene, Thermoplastics	Tin copper, PA66, PVC, ABS
Usage	Reusable, non-patient-contacting	Reusable and disposable, patient-contacting and non-patient-contacting
Sterilization	Non-Sterile	Non-Sterile

NONCLINICAL TEST DATA

Performance testing and analyses were performed on worst case representative cable assemblies and cable material to support substantial equivalence to the predicate device. Testing and analysis included the following:

- Cable assembly resistance and continuity testing
- Cable material signal integrity testing
- Electromagnetic interference and safety analysis

CONCLUSION FROM NONCLINICAL TEST DATA

The Fogg System Patient Monitoring Cables met all acceptance criteria from the testing and analyses and concluded to be in conformance to applicable sections of standards IEC 60601 and AAMI/ANSI BP22.

SUBSTANTIAL EQUIVALENCE CONCLUSION

The Fogg System Patient Monitoring Cables have the same intended use and indications for use as the predicate device. The subject devices use the same operating principle, incorporate the same basic design, configurations, and labeling as the predicate devices. Performance testing and analysis indicates conformance to the applicable sections of standards, the same as the predicate devices.

As such, the Fogg System Patient Monitoring Cables have been determined to be as safe and effective as the predicate device and no new or different questions were raised regarding the safety and effectiveness when compared to the predicate device. Therefore, the devices have been found to be substantially equivalent.

Table of Cables

Production Code	Description
7162-0XXX	Interface Cable - Connects specified Transducer Simulators to Compatible Monitors

7204-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7206-0XXX	Interface Cable - Connects specified Transducer Simulators to Compatible Monitors
7213-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7216-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7228-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7229-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7233-0XXX	Interface Cable - Connects specified Simulators to Compatible Monitors
7238-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7245-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7251-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7254-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7268-0XXX	Interface Cable - Connects specified Transducer Control Unit to Compatible Monitors
7279-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7286-0XXX	Interface Cable - Connects specified Simulators to Compatible Monitors
7287-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7295-0XXX	Interface Cable - Connects specified Pressure Wire Interfaces to Compatible Monitors
7297-0XXX	Interface Cable - Connects specified Simulators to Compatible Monitors
7303-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7304-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7305-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7307-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7310-0XXX	Interface Cable - Connects specified Transducer / Monitor Systems to Compatible Monitors
7316-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7330-0XXX	Interface Cable - Connects specified Transducer / Monitor Systems to Compatible Monitors
7339-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7340-0XXX	Interface Cable - Connects specified Transducer / Monitor Systems to Compatible Monitors
7342-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7343-0XXX	Interface Cable - Connects specified Simulators to Compatible Monitors
7353-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7354-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7360-0XXX	Interface Cable - Connects specified Transducer / Monitor Systems to Compatible Monitors
7364-0XXX	Interface Cable - Connects specified Transducer / Monitor Systems to Compatible Monitors
7367-0XXX	Interface Cable - Connects specified Transducer / Monitor Systems to Compatible Monitors
7368-0XXX	Interface Cable - Connects specified Transducer / Monitor Systems to Compatible Monitors

7378-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7379-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7380-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7381-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7383-0XXX	Interface Cable - Connects specified Transducer / Monitor Systems to Compatible Monitors
7389-0XXX	Interface Cable - Connects specified Transducers to Compatible Monitors
7161-0XXX-0XXX	Adapter Cable - Adapts Compatible Transducer with Interface Cable to a Compatible Monitor
7185-0756	Analog Cable - Cable for Pressure.
7185-0805	Analog Cable - Cable for Pressure.
7185-0809	Analog Cable - Cable for Pressure.
7242-0001	Analog Cable - Cable for Temperature Probe Simulator.
7242-0002	Analog Cable - Cable for Temperature Probe Simulator.
7242-0004	Analog Cable - Cable for Temperature Probe Simulator.
7242-0006	Analog Cable - Cable for Temperature Probe Simulator.
7242-0009	Analog Cable - Cable for Temperature Probe Simulator.
7335-0007	Analog Cable - Cable for ECG.
7335-0008	Analog Cable - Cable for ECG.
7349-0001	Analog Cable - Cable for ECG & Pressure.
7349-0002	Analog Cable - Cable for ECG & Pressure.
7349-0003	Analog Cable - Cable for ECG & Pressure.
7349-0005	Analog Cable - Cable for ECG & Pressure.
7349-0006	Analog Cable - Cable for ECG & Pressure.
7349-0008	Analog Cable - Cable for ECG & Pressure.
7349-0009	Analog Cable - Cable for ECG & Pressure.
7350-0001	Analog Cable - Cable for Pressure.
7350-0002	Analog Cable - Cable for Pressure.
7356-0001	Analog Cable - Cable for ECG & Pressure.
7356-0002	Analog Cable - Cable for ECG & Pressure.
7356-0003	Analog Cable - Cable for ECG & Pressure.
7356-0004	Analog Cable - Cable for Pressure.
7356-0005	Analog Cable - Cable for Pressure.
7356-0006	Analog Cable - Cable for ECG.
7356-0007	Analog Cable - Cable for ECG.
7356-0008	Analog Cable - Cable for Pressure.
7356-0014	Analog Cable - Cable for Pressure.
7356-0016	Analog Cable - Cable for ECG & Pressure.
7358-0012	Analog Cable - Cable for Pressure.
7382-0001	Analog Cable - Cable for Pressure.
7382-0002	Analog Cable - Cable for Pressure.
7382-0003	Analog Cable - Cable for Pressure.

7382-0004	Analog Cable - Cable for Pressure.
7382-0005	Analog Cable - Cable for Pressure.
7382-0006	Analog Cable - Cable for Pressure.
7382-0007	Analog Cable - Cable for Pressure.
7382-0008	Analog Cable - Cable for Pressure.
7382-0009	Analog Cable - Cable for Pressure.
7382-0010	Analog Cable - Cable for Pressure.
7390-0002	Analog Cable - Cable for Pressure.
7390-0004	Analog Cable - Cable for Pressure.