September 18, 2020

OBMedical Company
Paul E. Dryden
Consultant
3630 SW 47th Avenue, Suite 201
Gainesville, FL 32608

Re: K190798
Trade/Device Name: LaborView™ LV1000 Wireless Electrode System
Regulation Number: 21 CFR§ 884.2720
Regulation Name: External Uterine Contraction Monitor and Accessories
Regulatory Class: II
Product Code: OSP, HGM
Dated: September 3, 2020
Received: September 8, 2020

Dear Paul E. Dryden:

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,

Monica D. Garcia, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190798

Device Name
LaborView ™ LV1000 Wireless Electrode System

Indications for Use *(Describe)*
The LaborView ™ LV1000 Wireless Electrode System is a transabdominal electromyography and electrocardiography intrapartum maternal-fetal sensor. It works non-invasively via surface electrodes on the maternal abdomen with appropriate monitors to measure fetal heart rate (FHR), uterine activity (UA), and maternal heart rate (MHR). It is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies. It is intended for use by a healthcare professional in a clinical setting.

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.

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510(k) Summary

K190798

Date Prepared:	18-Sep-20
Sponsor:	OBMedical Company 3630 SW 47th Ave, Suite 201 Gainesville, FL 32608 Tel – 352-354-2244
Official Contact:	Minh Tam Nguyen, Director of Engineering
Submission Correspondent:	Paul E. Dryden ProMedic, LLC Tel – 239-307-6061
Proprietary or Trade Name:	LaborView™ LV1000 Wireless Electrode System
Common/Usual Name:	External uterine contraction monitor
Regulation Number/ Regulation Name:	21 CFR 884.2720 (External uterine contraction monitor and accessories) 21 CFR 884.2740 (Perinatal monitoring system)
Product Code:	OSP, uterine electromyographic monitor HGM, system, monitoring, perinatal
Regulatory Class:	Class II
Review Panel:	Obstetrics/Gynecology
Predicate Device:	K142583 Manufacturer: OB Medical Device Name: LaborView LV1000 The predicate device has not been subject to a design-related recall.

Device Description:

The LaborView™ LV1000 Wireless Electrode System is a uterine activity (UA), maternal (MHR) and fetal (FHR) heart rate sensor replacement intended to interface with existing Philips Avalon fetal monitors in hospital delivery environments.

LaborView™ LV1000 Wireless Electrode System is comprised of an electrode array, a wireless transmitter ("Transmitter"), computational base station ("Base Station"), a power supply module, and adapters to connect to compatible fetal monitors. The electrode array is sensitive to changes in the electrical activity at the skin surface due to muscle contractions, maternal, and fetal ECG when placed on the expectant mothers abdomen. These signals are passed to the device,

converted to a contraction curve, maternal heart rate (MHR), and fetal heart rate (FHR), and subsequently passed to the Philips monitor.

All the components of LaborView™ LV1000 Wireless Electrode System work together with the compatible fetal monitors to complete a system that can detect maternal contractions, MHR and FHR during labor. The fetal monitor, in turn, may interface to a central monitoring system in order to conveniently present contraction information to clinicians.

Indications for Use:

The LaborView™ LV1000 Wireless Electrode System is a transabdominal electromyography and electrocardiography intrapartum maternal-fetal sensor. It works non-invasively via surface electrodes on the maternal abdomen with appropriate monitors to measure fetal heart rate (FHR), uterine activity (UA), and maternal heart rate (MHR). It is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies. It is intended for use by a healthcare professional in a clinical setting.

Comparison of Intended Use and Technological Characteristics:

The following table compares the subject device to the predicate with respect to the indications for use and technological characteristics:

	Predicate Device **LaborView LV1000** **K142583**	**Subject Device** **LaborView™ LV1000 Wireless Electrode System** **K190798**
Indications for Use	LaborView LV1000 Wireless Electrode System is a transabdominal electromyography and electrocardiography intrapartum maternal-fetal sensor. It works non-invasively via surface electrodes on the maternal abdomen with appropriate monitors to measure fetal heart rate (FHR), uterine activity (UA), and maternal heart rate (MHR). It is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies. It is intended for use by a healthcare professional in a clinical setting	The LaborView™ LV1000 Wireless Electrode System is a transabdominal electromyography and electrocardiography intrapartum maternal-fetal sensor. It works non-invasively via surface electrodes on the maternal abdomen with appropriate monitors to measure fetal heart rate (FHR), uterine activity (UA), and maternal heart rate (MHR). It is indicated for use on women who are at >36 completed weeks, in labor, with singleton pregnancies. It is intended for use by a healthcare professional in a clinical setting.
Patient population	It is intended for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen	It is intended for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen
Prescriptive	Trained medical personnel	Trained medical personnel
Environments of use	Clinical settings	Clinical settings
Data collected from sensor array	Uterine Activity (UA) Fetal Heart rate (FHR) Maternal Heart rate (MHR)	Uterine Activity (UA) Fetal Heart rate (FHR) Maternal Heart rate (MHR)
Components of the "system"	Electrodes placed on abdomen (an array) Front-end wirelessly transmit data to receiver Back-end receiver connects to cleared fetal monitor Monitor to process and display data* * Does not include the monitor	Electrodes placed on abdomen (an array) Front-end wirelessly transmit data to receiver Back-end receiver connects to cleared fetal monitor Monitor to process and display data* * Does not include the monitor
Technology of measuring	Transabdominal electromyography and electrocardiography signals	Transabdominal electromyography and electrocardiography signals
Information displayed	On graphical monitor* *Utilizes the existing monitor to display the information	On graphical monitor* *Utilizes the existing monitor to display the information
Patient interface	Surface electrodes (array) -Single patient use, disposable	Surface electrodes (array) -Single patient use, disposable

The subject and predicate devices have the same intended use, i.e., measuring FHR, MHR, and UA. The subject and predicate devices have the same design, technology, and FHR output. They have different MHR and UA ranges. However, these differences do not raise different questions of safety and effectiveness

Non-Clinical Testing Summary:

Non-clinical testing was conducted to verify that the subject devices met all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:

Biocompatibility
Patient contacting components are in compliance with ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, including cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10) and irritation (ISO 10993-10).

Software Verification
Software documentation was provided in accordance with FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

Electrical Safety, EMC, and Wireless Capability
The subject devices were tested in compliance with the following:

- ANSI/AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

The sponsor provided documentation and recommended testing in accordance with FDA guidance document *Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff* issued August 14, 2013

Performance Testing
Bench testing was performed to verify the performance to specifications of the proposed device and included the following:

- Electrode Array Verification
- Transmitter (Front End) Verification
- Base Station (Back End) Verification
- Monitor Interface Cable Verification
- System Validation
- EC13 Compliance Verification for Maternal Heart Rate (MHR)
- Comparative Testing
- Testing with compatible patient monitors

Substantial Equivalence Conclusion:

The comparison and analysis above have demonstrated that the LaborView™ LV1000 Wireless Electrode System is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.