DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 7, 2017

Nemo Healthcare BV
Aron Wierts
Project Leader
De Run 4630
5504 DB, Veldhoven
The Netherlands

Re: K153262
Trade/Device Name: PUREtrace ™
Regulation Number: 21 CFR§ 884.2720
Regulation Name: External Uterine Contraction Monitor and Accessories
Regulatory Class: II
Product Code: OSP
Dated: January 26, 2017
Received: January 30, 2017

Dear Aron Wierts:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153262

Device Name
PUREtrace™

Indications for Use *(Describe)*
PUREtrace™ is an electromyography (EMG) device that non-invasively measures intrapartum uterine activity. PUREtrace™ is indicated for use on women who are at term (≥37 completed weeks), in labor, with singleton pregnancies. The signal is acquired from surface electrodes that are placed on the maternal abdomen. PUREtrace™ is intended for use by healthcare professionals 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.

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510(k) Summary
K153262

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Contact person: Aron Wierts
Date Prepared: 03-Feb-17

Proprietary or Trade Name: PUREtrace™
Common/Usual Name: External uterine contraction monitor
Classification: 21 CFR 884.2720
Classification Name: External uterine contraction monitor and accessories
Regulatory Class: II
Product code: OSP, uterine electromyographic monitor

Predicate Device: Monica Healthcare AN24 (K112390)

Device Description:
PUREtrace is a device for registering the electrical activity of the uterine muscle (myometrium) of laboring patients. PUREtrace consists of a multi surface-electrode patch (Graphium patch) and a hardware module (PUREtrace module). The Graphium patch is applied to the abdomen of the patient and acquires the electromyography (EMG) signal of the uterine muscle (electrohysterography, EHG). During a contraction, a large number of uterine muscle cells contract in a controlled manner and the changes in potential can be measured as changes in electrical potential on the skin of the pregnant woman's abdomen. This signal is sent to the PUREtrace module, converted into a measure for uterine activity and subsequently sent to a compatible fetal monitor where it is displayed as a tocogram. PUREtrace is available in multiple variants with different output connectors to facilitate interfacing with various fetal monitors.

Indications for use:
PUREtrace™ is an electromyography (EMG) device that non-invasively measures intrapartum uterine activity. PUREtrace™ is indicated for use on women who are at term (≥37 completed weeks), in labor, with singleton pregnancies. The signal is acquired from surface electrodes that are placed on the maternal abdomen. PUREtrace™ is intended for use by healthcare professionals in a clinical setting.

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

	Subject Device: PUREtrace K153262	**Predicate Device:** Monica AN24 K112390
Indications for Use	PUREtrace™ is an electromyography (EMG) device that non- invasively measures intrapartum uterine activity. PUREtrace™ is indicated for use on women who are at term (≥37 completed weeks), in labor, with singleton pregnancies. The signal is acquired from surface electrodes that are placed on the maternal abdomen. PUREtrace™ is intended for use by healthcare professionals in a clinical setting.	The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR), uterine activity (UA), and maternal heart rate (MHR). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG). The AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting.
Operating principle (for UA measurement)	Transabdominal electromyography	Transabdominal electromyography
System components / parts	• PUREtrace module (hardware module) • Patch cable • Graphium patch (sensor)	• Monica AN24 recorder/ monitor (hardware module) • Electrode cable connector • Electrodes (sensor) • Battery charger AN24
Patient interface (materials)	Surface electrodes incorporated in single electrode patch	Surface electrodes
Patient interface (use characteristics)	Single patient use, disposable	Single patient use, disposable
Power source	AC Mains power (50/60Hz) Class II medical grade power supply unit	Battery operated
Display of (uterine activity) information	Information to be displayed on an external fetal monitor	Information to be displayed on an external device, such as a fetal monitor

PUREtrace has the same intended use but different technological characteristics compared to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness.

Summary of non-clinical performance testing

Non-clinical tests were conducted to verify that PUREtrace met all design specifications and is substantially equivalent to the predicate. The test results demonstrated that the proposed device complies with the following standards:

- Biocompatibility testing per ISO 10993-1:2009 including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010) and irritation (ISO 10993-10:2010)
- Electrical Safety testing per IEC 60601-1:2005 + CORR. 1 (2006) + CORR.2 (2007) with US deviations per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012
- Electromagnetic Compatibility testing per IEC 60601-1-2:2007

Software verification and validation testing was also conducted as recommended in FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).

Summary of clinical performance testing

An observational clinical study has been conducted with an enrollment of 42 women at term and in active labor, who were simultaneously monitored on uterine activity (UA) with PUREtrace, tocodynamometry (TOCO) and intrauterine pressure catheter (IUPC). 40 UA registrations that consisted of sufficient useable data were assessed to evaluate the performance of PUREtrace. The tracings were reviewed by three individual clinical investigators, who were blinded to the technology used and the study subjects corresponding with the tracings. The clinical investigators assessed the interpretability of the tracings. In addition, they annotated the tracings by marking all deflections they assessed to be uterine contractions. The study demonstrated that PUREtrace performed substantially equivalent to the predicate device for displaying uterine activity of term pregnant women in active labor.

Substantial Equivalence Conclusion

Based on the comparison and analysis above, PUREtrace is substantially equivalent to the predicate device.