DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 24, 2017

Farus, LLC
Rahul Singh
President
1240 Keystone Way
Vista, CA 92081

Re: K171865
Trade/Device Name: F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal Monitoring System and Accessories
Regulatory Class: II
Product Code: HGM
Dated: June 20, 2017
Received: June 26, 2017

Dear Rahul Singh:

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,

Glenn B. Bell -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)*
K171865

Device Name
F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring

Indications for Use *(Describe)*
The F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring are intended for continuous wireless fetal monitoring indicated for pregnant women from about 22 weeks gestation through delivery: to be used during antepartum and intrapartum monitoring. This device is designed for use in singleton pregnancies only. It is not intended for home use.

The Ultrasound Transducer detects and evaluates the fetal heart rate during uterine contractions, and the Toco Transducer detects uterine contractions. The Transducers are to provide a means of sensing and functioning as a connection for signals to pass through from the patient to the monitoring or recording system. No other usage is intended for the transducers.

The system should only be used by, or under the direct supervision of, a licensed physician or other health care practitioner who is trained in the use of fetal heart rate monitors and in the interpretation of fetal heart rate traces.

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

K171865

1. Contact Information

Submitted by: Farus, LLC
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Vista, CA 92081

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Date Prepared: August 23, 2017

2. Device Information

Trade Name: F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring
Common Name: Transducers for Fetal Monitoring
Classification Regulation: 884.2740; Perinatal monitoring system and accessories
Classification: Class II
Product Code: HGM; system, monitoring, perinatal

3. Predicate Device

3.1 Predicate Device: Avalon CTS Cordless Fetal Transducer System
510(K) Number: K023931
Owned by: Philips Medical Systems
Nederland B.V. Post bus 10.000
5680 DA Best
Netherlands
Manufactured by: Philips Medizin Systeme Boeblingen GmbH
Cardiac and Monitoring Systems
Hewlett-Packard Str. 2
71034 Boeblingen
Germany

4. Device Description

The F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring is a perinatal monitoring accessory that integrates with GE Corometrics series monitors. The following table lists GE Corometrics series monitors that are compatible with the F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring:

Manufacturer and Model Number	510(k) Number
GE Corometrics 116	K891595
GE Corometrics 120 Series	K032252
GE Corometrics 126	
GE Corometrics 128/128F	
GE Corometrics 129/129F	
GE Corometrics 250 Series	K050583
GE Corometrics 250cx	
GE Corometrics 256	
GE Corometrics 259	
GE Corometrics 259cx	

The accessory's intended use is for antepartum and intrapartum wireless measurement and recording of fetal heart rate and maternal contractions. The intended use environment is a clinical setting, in the labor and delivery room of a hospital. The F1 is equipped with 1 Ultrasound (US) transducer, 1 Tocodynamometer (TOCO) transducer, and 1 Base Station. The Base Station transmits data wirelessly between the US/TOCO transducers (respectively) and a separate FDA-cleared fetal monitor ("monitor"), and is connected directly to the monitor via wired connection. The monitor must be used with the F1 accessory for display and recording of signals.

The Ultrasound and TOCO Transducers are water-resistant and may be used in the shower and tub during the first stage of labor, but not during the second stage of labor (underwater delivery), and should not be submerged or operated underwater. The Transducers may be used in the shower and tub in the same manner as when used away from water.

5. Indications for Use

The F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring are intended for continuous wireless fetal monitoring indicated for pregnant women from about 22 weeks gestation through delivery: to be used during antepartum and intrapartum monitoring. This device is designed for use in singleton pregnancies only. It is not intended for home use.

The Ultrasound Transducer detects and evaluates fetal heart rate during uterine contractions, and the Toco Transducer detects uterine contractions. The Transducers are to provide a means of sensing and functioning as a connection for signals to pass

through from the patient to the monitoring or recording system. No other usage is intended for the transducers.

The system should only be used by, or under the direct supervision of, a licensed physician or other health care practitioner who is trained in the use of fetal heart rate monitors and in the interpretation of the fetal heart rate traces.

6. Predicate Comparison

The following table compares the F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring to the predicate device with respect to indications for use, technological characteristics, and materials:

		F1 Mothership ireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring (K171865)	**Philips Avalon CTS (K023931)**
Intended Use			
Indications for Use Statement		The F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring are intended for continuous wireless fetal monitoring indicated for pregnant women from about 22 weeks gestation through delivery: to be used during antepartum and intrapartum monitoring. This device is designed for use in singleton pregnancies only. It is not intended for home use. The Ultrasound Transducer detects and evaluates fetal heart rate during uterine contractions, and the Toco Transducer detects uterine contractions. The Transducers are to provide a means of sensing and functioning as a connection for signals to pass through from the patient to the monitoring or recording system. No other usage is intended for the transducers. The system should only be used by, or under the direct supervision of, a licensed physician or other health care practitioner who is trained in the use of fetal heart rate monitors and in the interpretation of the fetal heart rate traces.	The Philips M2720A Cordless Fetal Transducer System is indicated for pregnant women from about 22 weeks of gestation on through delivery. It is intended for continuous cordless fetal monitoring in connection with a fetal monitor for resting or ambulating patients, also usable during hydrotherapy, for antepartum testing and labor and delivery (intrapartum). The system should only be used by, or under the direct supervision of, a licensed physician or other health care practitioner who is trained in the use of fetal heart rate monitors and in the interpretation of fetal heart rate traces. It is not intended for home use.
Physical Characteristics			

		F1 Mothership ireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring (K171865)	Philips Avalon CTS (K023931)
Weight	(With Transducers)	< 2.0 kg (4.4 lbs)	2.9 kg (6.4 lbs)
Dimensions	Base Station	278 x 207 x 65mm 11.0" x 8.2" x 2.6"	350 x 240 x 75mm 13.8" x 9.5" x 3.0"
	Probe	103 x 70 x 25mm 4.06"x2.76"x0.98"	100 x 76 x 37mm 3.94"x2.99"x1.46"
Materials			
US	Casing	ABS	ABS/Desmopan
TOCO	Casing	ABS	ABS/Desmopan
	Button	EVA	Desmopan
Belt		Polyester	Same
Technological Characteristics			
US	Mode of Operation	Pulsed wave Doppler	Same
	Center Frequency	1.151 MHz	1 MHz
	Peak-negative acoustic pressure	<30 kPa	Same
	Spatial-average temporal average intensity	<20 mW/cm^2	Same
	Accuracy	± 5%	Same
	Wired or Wireless	Wireless	Same
TOCO	Mode of Operation	Strain gauge	Same
	Pressure relationship	Monotonically increasing	Same
	Wired or Wireless	Wireless	Same
Base Station	Line-of-Sight Range	150 m	100 m
	Antenna	50 Ω	Same
	Water Ingress Protection Code	IPX1	Same

		F1 Mothership ireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring (K171865)	Philips Avalon CTS (K023931)
Power / Energy Source			
Battery	Type	Lithium ion	Same
	Capacity	1850 mAh	>700mAh
AC Mains (Base Station)	Supply Voltages	90-264 V	90-240 V
	Frequency Range	50-60 Hz	Same
	Power Consumption	40 W	15VA

The F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring have 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.

7. Performance Testing

7.1 Non-Clinical Tests

A series of tests were performed to verify the performance and safety of the F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring. These included:

- Electromagnetic Compatibility (EMC) Testing per IEC 60601-1:2007 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- FCC Test- CFR Title 47 Part 15 Subpart B and Industry Canada ICES-003
- Electrical Safety Testing per ANSI/AAMI 60601-1:2005/(R)2012 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance
- Mechanical Safety Test per ANSI/AAMI 60601-1:2005/(R)2012 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance
- Thermal Safety per IEC 60601-2-37 Medical electrical equipment- Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- Ingress Protection Code Test per IEC 60529 Degrees of protection provided by enclosures
- Biocompatibility Test – Patient-contacting materials used are equivalent to

those used in previously-cleared perinatal monitoring devices
- Validation Test – Simulated testing to gather feedback on usability of accessory and compare usability to standard fetal monitoring systems
- Battery Test – Bench testing to verify run time and charge time for transducers
- Wireless Range Test – Bench testing to verify wireless range of transducers
- Wireless Coexistence Test – Bench testing to verify transducers can coexist with other wireless equipment; used *"AAMI TIR69 Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems"* for guidance issued February 28, 2017
- Acoustic Output Test – Bench testing to verify acoustic parameters and safety of ultrasound transducer
- Code Compilation Summary Test- Software testing to verify prevention of memory leak
- Data Transmission Test – Software testing to verify data transmission between transducers and base station
- Pairing Verification Test – Software testing to verify pairing between transducers and base station
- Charging Verification Test – Software testing to verify operation in initiating and controlling battery charge
- System Performance Verification Test – Software testing to verify overall system performance by examining operations at various stages of charging
- TOCO Strain Performance Test – Software testing to verify TOCO transducer operation at the unit level
- US Performance Test – Software testing US transducer operation at the unit level
- TOCO Base Station Operations Test – Software testing to verify base station operation for the TOCO at the unit level
- US Base Station Operations Test – Software testing to verify base station operation for the US at the unit level
- Interoperability Test – Testing to verify Mothership system is compatible with claimed GE monitors

In addition, the following guidance documents were reviewed and consulted in preparing this document:
- "*Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*," Center for Devices and Radiological Health, FDA, 2008.
- "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices," Center for Devices and Radiological Health, FDA, 2005.
- *"General Principles of Software Validation; Final Guidance for Industry and FDA Staff,"* Center for Devices and Radiological Health, FDA, 2002.

- "*Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff,"* Center for Devices and Radiological Health, FDA, 2013.
- "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff",* Center for Devices and Radiological Health, FDA, 2014.
- *"Applying Human Factors and Usability Engineering to Medical Devices,"* Center for Devices and Radiological Health, FDA, 2011.

7.2 Clinical Tests

- Clinical Test
    - The hypothesis of this clinical study was that wireless electronic fetal monitoring (EFM) can provide equivalent performance to standard, wired EFM. We performed pilot clinical testing on pregnant women (n=5) to verify efficacy of the wireless EFM accessory in the measurement of the fetal heart rate (FHR) and uterine contractions in a simulated antepartum and intrapartum environment, as compared to standard wired EFM in order to demonstrate substantial equivalence.
- Clinical Measurement Accuracy Test
    - The Clinical Measurement Accuracy of both US and TOCO devices was tested using standard benchtop testing techniques common in the fetal monitoring industry. For the US transducer, accuracy was measured using a fetal heart rate simulator. The fetal simulator is able to provide discrete simulated fetal heart rates to the US transducers over a clinically meaningful range of several heart rates. The TOCO transducer was tested to verify that the device could measure pressure over a clinically-relevant range of pressures (simulating uterine contractions) in a monotonic fashion.

8. Performance Data and Conclusions

Based on the comparison and analysis above, the F1 Mothership Wireless Transducers for Fetal Ultrasonic and Tocodynamometer Monitoring is substantially equivalent to the predicate device.