July 2, 2024

Philips Medizin Systeme Boeblingen GmbH
Peng Cui
Principal Regulatory Affairs Specialist
222 Jacobs Street
Cambridge, Massachusetts 02141

Re: K233440
Trade/Device Name: Avalon CL Fetal & Maternal (F&M) Pod (866488),
Avalon CL Fetal & Maternal (F&M) Patch (989803196341)
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, OUG, OSP, DRX
Received: May 31, 2024

Dear Peng Cui:

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,

Monica D. Garcia -S

Monica D. Garcia, PhD
Assistant Director
DHT3B: Division of Reproductive,
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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.

510(k) Number *(if known)*
K233440

Device Name
Avalon CL Fetal & Maternal (F&M) Pod (866488);
Avalon CL Fetal & Maternal (F&M) Patch (989803196341)

Indications for Use *(Describe)*
The Avalon CL Fetal & Maternal (F&M) Pod & Patch is a device indicated for use by healthcare professionals in a clinical setting for non-invasive monitoring of maternal heart rate (aHR), fetal heart rate (aFHR), and uterine activity (aToco) in women who are at >36 completed weeks, in labor, with singleton pregnancy, using surface electrodes on the maternal abdomen.

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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510K SUMMARY
K233440

1. Submitter	
Date Prepared:	July 1, 2024
Submitter/Owner:	**Philips Medizin Systeme Böblingen, GmbH** Hewlett-Packard-Strasse 2 Böblingen, 71034 Germany Phone: +49 7031 4630 Fax: 07031-463 -2202 **FDA Registration:** FDA # 9610816
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510(k) Submission Type:	Traditional 510(k)

2. Device	
Trade Name(s):	Avalon CL Fetal & Maternal (F&M) Pod (866488) Avalon CL Fetal & Maternal (F&M) Patch (989803196341)
Common Name:	Fetal and Maternal monitoring- Pod & Patch
Regulation Name / Regulation Number:	21 CFR 884.2740 (Perinatal monitoring system and accessories)
Primary Product Code:	HGM (System, Monitoring, Perinatal)
Secondary Product Codes:	OSP (Uterine Electromyographic Monitor) DRX (Electrode, Electrocardiograph) OUG (Medical Device Data System)
Regulatory Class:	Class II
Review Panel:	Obstetrics/Gynecology

3. Predicate Device			
Predicate Device:	***510(k) No.***	***Company Name & Device Name***	***Product Code***
	K140862	*Company*: GE Healthcare *Device Name*: Monica Novii Wireless Patch System	HGM
The predicate device has not been subject to a design-related recall.			

4. Device Description [21CFR 807.92 (a) (4)]

The Avalon CL Fetal & Maternal (F&M) Pod and the Avalon CL Fetal & Maternal (F&M) Patch is a beltless battery-powered maternal-fetal monitoring system that non-invasively measures abdominal fetal heart rate (aFHR), abdominal uterine activity (aToco), and abdominal maternal heart rate (aHR).

The Avalon CL Fetal & Maternal (F&M) Pod & Patch is part of the Philips 'Avalon Cableless (CL) Solution' Family and consists of the following components:

- Avalon CL Fetal & Maternal (F&M) Patch (PN: 989803196341)
- Avalon CL Fetal & Maternal (F&M) Pod (PN: 866488)

The Avalon CL Fetal & Maternal (F&M) Patch is a single-use disposable adhesive electrode patch designed to be affixed to the maternal abdomen.

The Avalon CL Fetal & Maternal (F&M) Pod is a reusable device which, when connected to the Avalon CL Fetal & Maternal (F&M) Patch, picks up electrical signals and converts it to Short Range Radio (SRR).

The operating range is typically 'in-room', unless the subject device is used in conjunction with the Avalon CL Wide Range Pod (PN: 866487), an optional accessory.

The Avalon CL Fetal & Maternal Pod communicates the data measurement values to the Avalon CL Base Station using Short-Range Radio (SRR). The Avalon CL Base Station in turn relays the information to the connected Philips Fetal-Maternal (FM) Monitor (i.e., FM20, FM30, FM40, and FM50).

The Avalon CL Fetal & Maternal Pod's software release version is D.05.23.

The Avalon CL Fetal & Maternal Pod utilizes identical software infrastructure and radio from the cleared Philips IntelliVue CL Pods (K101600) - NiBP and SpO2 devices. The IntelliVue CL

Pods have a similar purpose and are used in similar environments as the Avalon Pod.

The Avalon CL F&M Patch does not have *software in a medical device* (SiMD). No software resides in the Avalon CL Fetal & Maternal Patch.

5. Indications for Use as required per 21 CFR 807.92(a)(5)

The Avalon CL Fetal & Maternal (F&M) Pod & Patch is a device indicated for use by healthcare professionals in a clinical setting for non-invasive monitoring of maternal heart rate (aHR), fetal heart rate (aFHR), and uterine activity (aToco) in women who are at >36 completed weeks, in labor, with singleton pregnancy, using surface electrodes on the maternal abdomen.

6. Comparison of Intended Use and Technological Characteristics for the Subject and Predicate Devices

	Subject Device Avalon CL Fetal & Maternal (F&M) Pod & Patch K233440	Predicate Device Monica Novii Wireless Patch System K140862	Comparison
Indications for use	The Avalon CL Fetal & Maternal (F&M) Pod & Patch is a device indicated for use by healthcare professionals in a clinical setting for non-invasive monitoring of maternal heart rate (aHR), fetal heart rate (aFHR), and uterine activity (aToco) in women who are at >36 completed weeks, in labor, with singleton pregnancy, using surface electrodes on the maternal abdomen.	The Monica Novii Pod 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 Novii Pod acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the Pod also acquires and displays the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG). The Pod is indicated for use on women who are at >36 completed weeks, in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. The Novii Patch is an accessory to the Novii Pod that connects directly to the Novii Pod and contains the surface electrodes that attach to the abdomen. The Novii Interface is an accessory to the Novii Pod which provides a means of interfacing the wireless output of the Novii Pod to	Similar

		the transducer inputs of a CTG Fetal monitor. The Novii Interface enables signals collected by the Novii Pod to be printed and displayed on a CTG Fetal Monitor and sent on to a central network, if connected. The Novii Pod maternal-fetal monitor and its accessories are intended for use by healthcare professionals in a clinical setting	
Anatomical site	Maternal abdomen	Maternal abdomen	Same
Measurement	Maternal Heart Rate Fetal Heart Rate Uterine Activity	• Maternal Heart Rate • Fetal Heart Rate • Uterine Activity	Same
Intended environments	Professional healthcare	Professional healthcare	Same
Target population	Women ≥ 36 gestational weeks with a singleton pregnancy	Women ≥ 36 gestational weeks with a singleton pregnancy	Same
Monitor Type	Electrodes - Electrical signals are passively monitored using five electrodes place on the pregnant abdomen in a fixed array.	Electrodes - Electrical signals are passively monitored using five electrodes place on the pregnant abdomen in a fixed array.	Same
Data transmission wireless technology	Short-Range-Radio (SRR), range 16ft (5m). The Avalon Wide Range Pod is offered as an optional accessory to extend the Avalon CL F&M Pod signal's range.	Bluetooth, range - 100ft (30m)	**Different**
Power source	Battery (Li-ion battery)	Battery (Li-Po battery)	**Different**
Patch Shelf-life	1 year	2 year	**Different**
Use life of the Pod	500 cycles/4 years	4.7 years	**Different**
Patch size	161mm x 190mm	160mm x 185mm	**Different**
Measurement method (FHR/MHR)	Abdominal electrophysiological signal and template matching, filtering and confidence tagging to identify the fECG and mECG complexes from other signals and interference/noise. R-R interval detection to determine FHR & Maternal HR.	Abdominal electrophysiological signal and template matching, filtering and confidence tagging to identify the fECG and mECG complexes from other signals and interference/noise. R-R interval detection to determine FHR & Maternal HR.	Same
Measurement method (uterine activity)	Uterine electromyography (EMG) signals to obtain uterine contractions (aToco)	Uterine electromyography (EMG) signals to obtain uterine contractions (UA)	Same
Data Interface	*Avalon CL Base Station* (K140535) **only** captures measurements received from the Avalon CL F&M Pod and sends them to the Philips Avalon Fetal Monitor (FM) for	*CTG Interface* - capture and display the measurements received from the Monica Novii Pod	**Different**

	display.		
Charging ports	One dedicated port for the charging of the Avalon CL F&M Pod on the *Avalon CL Base Station* (K140535)	Two dedicated ports for charging of the Monica Novii Pods	**Different**

The subject and predicate devices have the same intended use, i.e., measuring FHR, MHR, and UA. The subject and predicate devices have the similar design, technology, and FHR output. They have different power sources, wireless technology, data interfaces, patch shelf-life, pod use-life and number of charging ports for pods. However, these differences do not raise different questions of safety and effectiveness.

7. Performance Data

Non-Clinical Tests – Recognized Consensus Standards

The Avalon CL F&M Pod & Patch has passed all safety tests for demonstrated compliance with the consensus standards listed below:

Standard	FDA Recognition #	Title #
ISO 10993-5	2-245	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	2-174	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ANSI AAMI ES60601-1	19-4	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2	19-36	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEEE ANSI C63.27	19-29	American National Standard for Evaluation of Wireless Coexistence
IEC/TR 60601-4-2	19-19	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

IEC 60601-1-8	5-76	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62133-2	19-33	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Non-Clinical Tests

1. *Sterilization and Shelf Life*
   Sterilization is **not** applicable to the Avalon CL F&M Pod &Patch. The subject device **is not** designed to be sterilized or sterilizable.

   The Avalon CL F&M Patch is a single-use, single-patient device and is disposed of upon removal or completion of treatment. The Avalon CL F&M Pod is a reusable device that has been verified and validated (V&V) for cleaning and disinfection.

2. *Biocompatibility*
   The patient contacting components of the subject device met the acceptance criteria as defined in the test requirements. Tests were conducted based on contact and duration, as outlined in ISO 10993-1.
   - Cytotoxicity (ISO 10993-5)
   - Sensitization (ISO 10993-10)
   - Irritation (ISO 10993-10)

3. *Software/Firmware & Cybersecurity/Interoperability*
   The GE proprietary algorithm converts the Avalon CL Fetal & Maternal (F&M) Patch's electrical signals and converts it to usable signals to the Avalon CL F&M Pod. The pod relays the numerical results (aFHR, aHR, and aToco) to the cleared Avalon CL Base Station (K140535) using the SRR Radio Transceiver & Antenna. The IEEE 802.15.4 SRR interface board contains an on-board, integrated transceiver and antenna.

   The Avalon CL Fetal & Maternal Pod utilizes identical software infrastructure and radio from the cleared IntelliVue CL Pods (K101600) - NiBP and SpO2 devices. The IntelliVue CL Pods have a similar purpose and are used in similar environments.
   Additionally, the SRR technology is cleared under Philips Avalon CTS Cordless Fetal Transducer System (K023931) and Avalon CL Base Station (K140535).

   Verification and Validation (V&V) testing has been conducted to ensure the safety, performance, interoperability, and effectiveness of the subject device.

Software documentation was provided in accordance with FDA guidance document "Content of Premarket Submissions for Device Software Functions (fda.gov)" issued June, 2023.

The sponsor also provided cybersecurity documentation for the subject device per the 2023 FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (fda.gov)".

4. *EMC, Wireless, Electrical, Mechanical and Thermal Safety*
   The subject devices met the acceptance criteria as defined in the test requirements per the standards listed above and 2022 FDA guidance "Electromagnetic Compatibility (EMC) of Medical Devices (fda.gov)".

5. *Performance - Bench*
   The subject devices met the acceptance criteria as defined in the test requirements. The following performance tests were conducted for the subject device:
   - Inspection of the labelling and pouch sealing (Novii Patch)
   - Impedance/tensile strength/pull-off force/noise level/conductivity/offset voltage/defibrillation overload for newly manufactured and aged (12 month) patches. (Novii Patch and Avalon Patch)
   - In vivo testing: integrity, detachment/reattachment, and performance (impedance, noise level, MHR, conductivity) after shower and usage (8 hours/32 hours) for the patch (Novii Patch).
   - Peel-off force of each electrode and central sticker (Novii Patch and Avalon patch).
   - MHR/FHR/UA accuracy after stored in room (23°C), high (32°C) and low (2-8°C) temperature (Novii Patch).
   - Signal transmission continuity (Avalon Pod and patch).

8. Conclusions

The non-clinical testing discussed above demonstrates that the Avalon CL Fetal & Maternal (F&M) Pod and Avalon Fetal & Maternal (F&M) Patch (*Subject Device*) is as safe and effective as the predicate device.