January 10, 2025

PeriGen, Inc.
Candace Alva
Director of Regulatory Affairs and Quality Assurance
Sderot Nim 2, P.O. Box 110
Rishon LeTziyon, 7510002
Israel

Re: K241009
Trade/Device Name: PeriCALM Patterns 3.0
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal Monitoring System and Accessories
Regulatory Class: II
Product Code: HGM
Dated: December 11, 2024
Received: December 11, 2024

Dear Candace Alva:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241009

Device Name
PeriCALM Patterns 3.0

Indications for Use *(Describe)*
PeriCALM Patterns is intended for use to provide additional secondary information as an adjunct to qualified clinical decision-making during antepartum or intrapartum obstetrical monitoring at ≥32 weeks gestation for annotation and summary of the fetal heart rate recording for baseline, accelerations and decelerations and the uterine pressure recording for contractions.

WARNING: Evaluation of FHR during labor and patient management decisions should not be based solely on PeriCALM Patterns annotations or summaries and should include inspection of the fetal monitor tracing and consideration of all pertinent clinical information.

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
PeriCALM Patterns 3.0 – K241009

Date Summary Prepared:	January 10, 2025
Submitter Information	
Submitted by:	PeriGen Solutions, Ltd Sderot Nim 2, PO Box 110, Rishon LeTziyon, 7510002, Israel
Telephone:	+972-3-905-9900
Contact Person:	Natan Blanks GM, Israel Operations
Subject Device Information	
Device Trade Name:	PeriCALM Patterns 3.0
Common Name:	Computer-based information management system for obstetrical care
Regulation Name:	Perinatal monitoring system and accessories
Regulation Number	21 CFR 884.2740
Device Panel:	Obstetrics/Gynecology
Product code:	HGM (system, monitoring, perinatal)
Regulatory Class:	II
Predicate Device Information	
Predicate Device:	CALM Patterns PeriGen Solutions, Ltd. (Also listed as PeriCALM Patterns) The predicate device has not been subject to a design-related recall
510(k) Number	K040788
Device Description	

PeriCALM Patterns 3.0 is a software device to be used with fetal/maternal monitoring systems. The subject device is a software algorithm to detect, label and measure features (accelerations, decelerations, baseline, and contractions) in electronic fetal monitoring (EFM) records. PeriCALM Patterns 3.0 uses fetal monitor data imported through an interface with an external source or with a third-party clinical information system. PeriCALM Patterns can function in a networked environment or as a standalone workstation.

The subject device includes present-day Long and Short-Term Memory (LSTM) neural networks to identify segments of a fetal heart rate tracing corresponding to accelerations, decelerations, baseline as well as uninterpretable segments where there is missing tracing. Contraction detection is achieved using the same processes as the predicate device.

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Indications for Use
PeriCALM Patterns is intended for use to provide additional secondary information as an adjunct to qualified clinical decision-making during antepartum or intrapartum obstetrical monitoring at ≥32 weeks gestation for annotation and summary of the fetal heart rate recording for baseline, accelerations and decelerations and the uterine pressure recording for contractions. **WARNING:** Evaluation of FHR during labor and patient management decisions should not be based solely on PeriCALM Patterns annotations or summaries and should include inspection of the fetal monitor tracing and consideration of all pertinent clinical information.

Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Device

	Subject Device PeriGen – PeriCALM Patterns 3.0 K241009	**Predicate Device PeriGen – PeriCALM Patterns K040788**
Intended Use	PeriCALM Patterns is intended for use to provide additional secondary information as an adjunct to qualified clinical decision-making during antepartum or intrapartum obstetrical monitoring at ≥32 weeks gestation for analysis of the fetal heart rate recording for baseline, accelerations and decelerations and the uterine pressure recording for contractions. WARNING: Evaluation of FHR during labor and patient management decisions should not be based solely on PeriCALM Patterns annotations or summaries and should include inspection of the fetal monitor tracing and consideration of all pertinent clinical information.	CALM Patterns is intended for use as an adjunct to qualified clinical decision-making during antepartum or intrapartum obstetrical monitoring at ≥36 weeks gestation to obtain annotation of the FHR for baseline, accelerations, and decelerations. WARNING: Evaluation of FHR during labor and patient management decisions should not be based solely on CALM Patterns annotations.
Applicable gestational age	≥32 weeks	≥36 weeks
Data Collection	Collects FHR and uterine activity data from electronic maternal/fetal monitors.	Collects FHR and uterine activity data from electronic maternal/fetal monitors.
Sample Rate	Samples FHR at a minimum of four samples per second. Samples uterine activity at a minimum or 1 sample per second.	Samples FHR at a minimum of four samples per second. Samples uterine activity at a minimum or 1 sample per second.

Pattern recognition module core technology	Signal processing and neural networks	Signal processing and neural networks
Neural network interference: combined accel-decel-baseline + non-interpretable detection	Yes	No
Measurement and labeling accelerations on the tracing	Yes	Yes
Baseline measurements	Yes	Yes
Contraction measurements	Yes	Yes
Analysis provided and summarized in time intervals	15 or 30 minutes	20 minutes
Provides users with the option to select, modify and export a set of summarized measurements.	Yes	Yes
Displays a long-term compressed view of tracing	Yes	Yes
Summarizes measurements with the long-term view.	Yes	Yes
Handling of disagreements between algorithm detected patterns and clinician opinion	User can delete a feature annotation	User can add, modify or delete a feature annotation.
Non-interpretable segments where there is missing tracing	Yes	No

The indications for use of PeriCALM Patterns 3.0 are similar to the predicate device and the subject and predicate device have the same intended use – as an adjunct to clinical decision making during antepartum, or intrapartum monitoring. The subject device has an extended gestational age from ≥ 32 weeks, compared to the predicate device which has a gestational age from ≥ 36 weeks. This difference in gestational age does not raise different questions of safety and effectiveness.

The technological differences between the subject and predicate device include the addition of neural network interference (combined accel-decel-baseline + non-interpretable detection), different time intervals of analysis, and differences in the managements of non-interpretable segments for a missing trace. These differences do not raise different questions of safety and effectiveness as compared to the predicate device.

Summary of Non-clinical Performance Testing

Software and Cybersecurity

Software was evaluated as recommended in the 2023 FDA guidance document "*Content of Premarket Submissions for Device Software Functions*." The following activities were successfully completed:

- Risk Analysis / Management
- Requirements Reviews
- Design Reviews
- Software Verification and Validation

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The successful V&V tests demonstrate that the device performs in accordance with specifications. Cybersecurity was evaluated as recommended in the 2023 FDA guidance document "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*."

Summary of Clinical Performance Testing

A retrospective study with multi-reader/multi-case technique was used to determine if the performance of PeriCALM Patterns 3.0 is not inferior to that of a set of qualified and experienced Obstetrician Gynecologists called the Clinician Readers. The predicate device was cleared for use in gestational ages of ≥36 weeks comparing to Ground Truth and Clinician Readers. The same approach was taken for this study, comparing PeriCALM Patterns 3.0 to Ground Truth and Clinician Readers for two gestational age subgroups: ≥36 weeks (term) and 32-35 weeks (pre-term). The ground truth for this study is established by a panel of 3 experts, called the "Truthers". To resolve the inter-observer variation, a majority opinion approach was used. The results of the comparison of the subject device to ground truth is to be non-inferior to the results of the comparison of Readers to ground truth.
A total of 70 subjects (30 preterm and 40 term), with one tracing per subject, were used in the study. Tracings were obtained from hospitals using a variety of fetal monitor models and manufacturers including Corometrics 170, 250 series by GE HealthCare, Avalon FM50 and FM40 by Philips Medical, and S1 from Neoventa and included both antepartum and intrapartum recordings. The tracings were selected from pregnancies with gestational ages from 32 weeks to term, covering a wide range of operating and clinical conditions with respect to maternal BMI, delivery modes, fetal birth weights, hospital types, Apgar scores and antepartum or intrapartum usage.
The study included sixteen (16) co-primary endpoints with different acceptance criteria for non-inferiority. Twelve (12) co-primary endpoints pertained to accelerations and decelerations for both gestational groups (i.e., Term and Preterm) and included performance metrics (Sensitivity (Se), Specificity (Sp), Positive Predictive Value (PPV)) of the subject device compared to those of the Readers. Remaining four co-primary endpoints focused on the FHR baseline measurements and were based on Bland-Altman analyses to determine bias, the mean difference between two methods and the Limits of Agreement (LoA) which include 95% of the differences between the two measurement methods. Inferiority margin of 15% for acceleration and deceleration detection and 10% for baseline level was used. The acceptance criteria for 95% CI of Bias for the subject device was set to threshold of ≤ 5 bpm.
PeriCALM Patterns 3.0 passed all acceptance criteria on performance testing regarding pattern detection.

Conclusion

The performance data described above demonstrate that the PeriCALM Patterns 3.0 is as safe and effective as the PeriCALM Patterns (K040788) and supports a determination of substantial equivalence.

PeriGen Solutions Ltd.
Azrieli Rishonim | 2 Nim Blvd.
POB 110 Rishon LeZion 7510002
Israel
| t: +972.3.905.9900
| f: +972.3.971.2880