September 29, 2023

PyrAmes Inc.
Isabella Schmitt
Director of Regulatory Affairs
2450 Holcombe Blvd
Houston, Texas 77021

Re: K223873
Trade/Device Name: Boppli Infant Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: QYF
Dated: December 23, 2022
Received: December 23, 2022

Dear Isabella Schmitt:

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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223873

Device Name
Boppli Infant Blood Pressure Monitor

Indications for Use *(Describe)*
The Boppli Infant Blood Pressure Monitor is indicated for use by medically trained personnel in clinical settings, such as the NICU, PICU, CVICU, and emergency or operating room, to continuously monitor diastolic, systolic, and mean arterial blood pressures of neonates and infants, under 5 kilograms in weight, who have a palpable pulse.

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

510(k) Owner:	PyrAmes, Inc. 21730 Stevens Creek Blvd, Suite 201A Cupertino, CA 95014
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Representative Consultant Contact:	Isabella Schmitt, RAC, MBA Proxima Clinical Research, Inc. 2450 Holcombe Blvd, Suite J Houston, TX 77021 Telephone: +1-832-463-1409 E-mail: Isabella@ProximaCRO.com
Date Summary Prepared:	28 September 2023
Trade Name:	Boppli Infant Blood Pressure Monitor
Common Name:	System, Measurement, Blood-Pressure, Non-Invasive
Classification:	Class II
Classification Number:	21 CFR 870.1130
Product Code(s):	QYF
Classification Advisory Committee:	Cardiovascular

Predicate Device(s): TL10 Tensymeter Blood Pressure Monitoring System (K020537)

Device Description:

The Boppli Infant Blood Pressure Monitor, or Boppli Device, is a non-invasive blood pressure monitor that utilizes a reusable mobile tablet electronic interface (Boppli Bedside) with a single-use non-invasive sensor band (Boppli Band) that is placed on the arm or leg of an infant over a palpable pulse point, such as the radial or dorsalis pedis artery, respectively. The device uses proprietary algorithms to derive the arterial pressure and display systolic (SBP) and diastolic blood pressure (DBP), mean arterial pressure (MAP), pulse rate (PR), and a continuous pressure waveform. The device allows healthcare providers to monitor a neonate's blood pressure in clinical settings.

Indications for Use:

The Boppli Infant Blood Pressure Monitor is indicated for use by medically trained personnel in clinical settings, such as the NICU, PICU, CVICU, and emergency or operating room, to continuously monitor diastolic, systolic, and mean arterial blood pressures of neonates and infants, under 5 kilograms in weight, who have a palpable pulse.

Technological Characteristics:

The technological characteristics of the Boppli Infant Blood Pressure Monitor are substantially equivalent to the technological characteristics of the predicate device. Both devices are considered NIBP monitors based on the principle of tonometry, which is applied to the patient's artery to measure changes in pressure. The sensor technology differs, in that the predicate device uses a single semiconductor pressure-sending element worn on the wrist while the Boppli employs a capacitance-based sensor placed on the leg or the wrist. However, the devices operate on the same underlying principles in which proprietary algorithms use the sensor data to derive a pressure waveform and resulting blood pressure values, including SBP, DBP, and MAP, for review and interpretation by a healthcare provider. Both devices operate without external calibration, and while the predicate utilizes an algorithm to define an optimum pressure sensing position over the artery, Boppli uses a sensor array and a quality metric to ensure data of sufficient quality are analyzed and presented to users. There is a difference in intended patient population between the Boppli device and the predicate; however, the Boppli intended patient population is under supervision and SpO2 monitoring. As such, any differences in technological characteristics between Boppli and the predicate device do not raise new and different questions of safety and effectiveness, and device performance has been verified through both clinical and nonclinical testing.

Biocompatibility Testing:

Cytotoxicity, sensitization, and irritation testing was performed on the patient-contacting components of the device per FDA-recognized standard ISO 10993-1:2018 and the FDA Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'" There were no cytotoxicity, sensitization, or irritation concerns associated with the Boppli Sensor Band.

Electrical Safety and EMC Testing:

The Electrical Safety (ES) and Electromagnetic Compatibility (EMC) testing conformed to ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009 / (R)2012 and A2:2010 / (R)2012, IEC 60601-1-2 Edition 4.0 2014-02, IEC 60601-1-6 Edition 3.1 2013-10, IEC 60601-1-8 Edition 2.1 2012-11, and FCC Part 15 Subpart B. All acceptance criteria were met for the Boppli Sensor Band and Bedside Device.

Software Testing:

The software used in the Boppli Infant Blood Pressure Monitor has been determined to be a moderate level of concern. Software verification and validation testing were conducted, and documentation has been provided in accordance with FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Bench Performance Testing:

Bench performance testing verified that the Boppli Sensor Band and Bedside Device met the specified requirements for signal processing and data transmission, accelerometer data acquisition, battery runtime, device deployment time, BLE range, channel selection and quality verification, operating systems, and hardware platforms.

Human Factors / Usability Engineering Testing:

Through usability testing, the Boppli was found to be substantially equivalent for the intended users, uses, and use environments. Furthermore, any further modifications to the user interface, including the device and labeling, would not further reduce risk, are not possible, or are not practicable, and the remaining residual use-related risks are outweighed by the benefits derived from the used of the device.

Animal Testing:

Animal testing was not performed for this device.

Clinical Testing:

A prospective, multi-center clinical study was performed to validate the effectiveness of the Boppli Infant Blood Pressure Monitor as compared to an invasive arterial reference in neonates and infants under 5 kg in weight who required invasive blood pressure monitoring. The study included 79 subjects representing the intended patient population and was validated in the blood pressure range applicable to the intended patient population. The study evaluated the accuracy, precision, and stability of the Boppli System for continuous non-invasive blood pressure monitoring by comparing SBP, DBP, MAP, and pulse waveform against the reference methodology. The stability was performed over the intended use life of 72 hours. The accuracy of the stability was evaluated for each 6-hour period.

The primary endpoint was the mean average error (MAE) and standard deviation (SD) of the difference of the paired measurements between the device and the intraarterial line (IAL) reference for SBP, DBP, and MAP, assessed separately. The primary endpoint goal was the MAE <= ± 5 and SD < = 8 mmHg for each of the blood pressure outputs (SBP, DBP, and MAP). In addition to the accuracy test, a stability test was used to assess the accuracy over the duration of use of the device. Additionally, the device's ability to detect changes in blood pressure occurring over a 3-minute interval was evaluated considering the intended patient population blood pressure range. The secondary endpoint for this study was analysis of observed device-related adverse events.

Mean Average Error (MAE) and Standard Deviation (SD) [mmHg]							
Analysis Method	N Subjects (N Points)	MAP		SBP		DBP	
		MAE	SD	MAE	SD	MAE	SD
Method A: ISO 81060-2: MAE and SD of values observed at 10-min analysis periods for the first 6 hours of data collection	79 (735)	1.0	7.5	-0.8	10.5	2.1	6.6
Method B: ANSI/AAMI SP10: Average and SD of individual subject MAE values over entire data collection period	79	0.7	5.3	-0.8	7.7	1.4	4.7
Band Error Calculation							
Method A	79 (741)	0.8	6.5	-0.8	9.1	1.6	5.7
Method B	79	0.7	5.1	-0.7	7.4	1.4	4.5

As can be seen in the table above, the device missed the primary endpoint for the systolic blood pressure. Given the intended use population, the high-acuity environment, and conjunction with SpO2 monitoring, the higher standard deviation was determined to be acceptable. The pulse rate was evaluated in the clinical study as well. The expected error of the pulse rate was within 5% of the actual bpm. The device met the accuracy

requirement.

Conclusion:

In conclusion, the PyrAmes Boppli Infant Blood Pressure Monitor has demonstrated to be substantially equivalent to the identified predicate device. The PyrAmes Boppli Infant Blood Pressure Monitor has the same intended use, technological characteristics, and principles of operation as the predicate. Any differences in indication between the PyrAmes Boppli Infant Blood Pressure Monitor and the predicate device do not alter the intended use of the device, and differences in technological characteristics do not raise new or different questions regarding its safety and effectiveness when used as labeled. Verification, validation, usability, and clinical testing demonstrate that the device performs as intended. While the primary endpoint was missed for the systolic blood pressure, due to the context of use and intended use population, it was determined to be substantially equivalent to the predicate. Thus, the PyrAmes Boppli Infant Blood Pressure Monitor is substantially equivalent to the identified predicate device.