July 2, 2025

Aktiia SA
Neil Puri
Head of Quality and Regulatory Affairs
Rue du Bassin 8a
Neuchâtel, 2000
Switzerland

Re: K250415
Trade/Device Name: G0 Blood Pressure Monitoring System (G0)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 6, 2025
Received: June 6, 2025

Dear Neil Puri:

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,

Hetal B. Odobasic -S

for

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250415

Device Name

G0 Blood Pressure Monitoring System (G0)

Indications for Use *(Describe)*

The Aktiia G0 Blood pressure monitoring system consists of a wrist worn monitor and an oscillometric cuff. The system is intended for measuring blood pressure and pulse rate based on using a Pulse Wave technique in adults aged from 22 to 59 years old with wrist circumference ranging from 14 cm to 21 cm following a calibration process (every 24 hours) using the oscillometric blood pressure cuff.

The Aktiia G0 Blood pressure monitoring system is intended for spot-checking of adult patients for home use.

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

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Aktiia SA
Applicant Address	Rue du Bassin 8a Neuchatel N/A 2000 Switzerland
Applicant Contact Telephone	808-284-4774
Applicant Contact	Mr. Neil Puri
Applicant Contact Email	neil.puri@aktiia.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	G0 Blood Pressure Monitoring System (G0); Aktiia Init I1 (I1)
Common Name	Noninvasive blood pressure measurement system
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number	870.1130
Product Code(s)	DXN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190792	BB-613 WP	DXN
K240254	Blood Pressure Monitor (TMB-2296-BT)	DXN

Device Description Summary

21 CFR 807.92(a)(4)

The Aktiia G0 Blood Pressure Monitoring System measures blood pressure and pulse rate (spot check) based on the analysis of Photoplethysmography (PPG) signals. Aktiia G0 Blood Pressure Monitoring System consists of the following components:

- Bracelet
- Charger (for the Bracelet)
- Aktiia Init I1 (cuff)
- Mobile App
- Backend Software and Algorithm (in the Cloud)

The Aktiia G0 Blood Pressure Monitoring System hardware component, referred to as the bracelet, is responsible for PPG data acquisition on the user's wrist. It is composed of a data logging unit called the pod and of a detachable strap that is intended to secure the pod to the user's wrist. The pod houses the bracelet's electronics and PPG sensor. The bracelet's internal battery is located inside the pod and is recharged using a pin to USB docking station using a provided charger.

A calibration process (also referred to as initialization) is required prior to converting blood pressure values from optical data. This calibration process uses reference blood pressure values measured with an oscillometric blood pressure monitor (cuff) also referred to as Aktiia Init I1.

The Aktiia G0 Blood Pressure Monitoring System includes a mobile application for displaying data to the user and uses a cloud server referred to as the backend for data storage. The backend also hosts the algorithm which converts optical data generated by the bracelet

into blood pressure and pulse rate data.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Aktiia G0 Blood pressure monitoring system consists of a wrist worn monitor and an oscillometric cuff. The system is intended for measuring blood pressure and pulse rate based on using a Pulse Wave technique in adults aged from 22 to 59 years old with wrist circumference ranging from 14 cm to 21 cm following a calibration process (every 24 hours) using the oscillometric blood pressure cuff.

The Aktiia G0 Blood pressure monitoring system is intended for spot-checking of adult patients for home use.

Indications for Use Comparison

21 CFR 807.92(a)(5)

G0 Blood Pressure Monitoring System:
Both the subject and predicate devices are intended to track blood pressure changes in an adult population and home-use environment by transforming optical signals using a pulse-wave based algorithm, following a calibration process. Both devices are wrist worn devices intended to record optical data from an individual's wrist and have the same contact classification and duration.

Both the subject device and predicate device are indicated for spot check measurements of blood pressure and pulse rate for home use.

The predicate device has additional indications than the subject device which includes monitoring of functional oxygen saturation of arterial hemoglobin and an intended use beyond home use which includes hospitals, clinics, and long-term care. These broader indications are not included in the indications of the subject device.

These additional indications do not impact the similarities between the intended use of the subject device and the predicate device as both devices have the same intended use related to blood pressure and pulse rate monitoring.

Aktiia Init I1 (Cuff):
The predicate device for the cuff has the same intended use as the subject device.

Technological Comparison

21 CFR 807.92(a)(6)

G0 Blood Pressure Monitoring System:

Sensing Technology
Both devices use reflective photoplethysmography (PPG) sensing technologies. The Aktiia G0 Blood pressure monitoring system makes use of a green LED emission while the Biobeat (BB-613WP) predicate device uses red and infrared LEDs emission. The safety of the green LED emission of the Aktiia G0 Blood Pressure Monitoring system was verified to meet the requirements of IEC 62471. Moreover, the capability of the green LED to capture PPG signals on a range of skin color tones was demonstrated through clinical studies. There are significant technological similarities between both devices and the minor differences do not raise any new questions related to safety and effectiveness in regard to the subject device.

Power Supply and Bluetooth Radiotechnology
Both devices are battery powered and contain electronics that make use of Bluetooth radio technology to transfer data. Both devices are IEC 60601-1-2:2014 compliant for electromagnetic compatibility and IEC 60601-1 for electrical safety and are validated for home use according to IEC 60601-1-11:2015. Lastly, the subject device's Bluetooth module is compliant with ETSI 300328 for radio emissions limits.

Software, Calibration, and Data Analysis
Both devices use software for data acquisition, data analysis, data storage and both devices use a mobile device as an external display unit for data visualization. The Aktiia G0 blood pressure monitoring system differs from the predicate device in the following aspects:

i) the algorithm responsible for blood pressure estimation is not embedded on the device itself but on a secured cloud server and

ii) the computed data are stored on a secured cloud server and not on a mobile device.

To ensure safety and effectiveness, all software elements in the Aktiia G0 blood pressure monitoring system were developed and validated per IEC 62304:2006 and FDA Guidance. Both devices require a calibration process using an oscillometric blood pressure monitor. Both devices use similar pulse-wave based algorithms for evaluation of blood pressure from optical data. While the Aktiia G0 blood pressure monitoring system makes use of a Pulse-Wave Analysis (PWA) algorithm, the BB-613WP predicate device makes use of a Pulse-Wave Transit Time (PWTT) algorithm. Both algorithms utilize the same pulse-wave principle that tracks blood pressure changes by detecting changes in the elasticity of the arteries as measured from optical data.

ISO 81060-2 Standard Compliance
Aktiia performed clinical testing to validate the accuracy and precision of the measured blood pressure in the seated and relaxed position for a representative US population cohort. When comparing the blood pressure measurements of a reference method (double auscultation) against the blood pressure measurements from the Aktiia G0 blood pressure monitoring system, it was shown that the subject device achieves the clinical accuracy and precision requirements of ISO 81060-2, thus showing that the subject device meets or exceeds the level of effectiveness of the predicate device.

Conclusion:
In summary, Aktiia's subject device and the predicate device (Biobeat) are substantially equivalent. Both have very similar indications for use with Aktiia's device having the same indication for providing spot check measurements of blood pressure and pulse rate. Both devices use an optical sensor for measuring both blood pressure and pulse rate and utilize similar pulse-wave principles in converting optical sensor data to blood pressure and pulse rate data. Although there are minor differences related to the use of specific optical wavelengths in the technological characteristics between the subject device and its predicate, these differences do not raise questions of safety or effectiveness, and the testing established equivalent safety and effectiveness between the subject and predicate device.

Aktiia Init I1 (cuff)
The subject device and predicate device have the same technological characteristics. They both measure blood pressure and pulse rate in adults using the oscillometric method where the cuff is placed on the upper arm. Both devices utilize a rechargeable battery and are capable of transmitting the data via bluetooth to connected devices. Both devices use similar materials and have completed biocompatibility testing in compliance with ISO 10993-1.

The only minor difference in technologies between the two devices is that predicate device has an LCD display and the subject device displays blood pressure value and pulse rate in Aktiia's mobile application. This difference does not impact the safety and effectiveness between the two devices as the information being displayed (blood pressure and pulse rate) is the same. Usability testing has been performed to validate that the display of the cuff data in the Aktiia mobile application does not impact safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance data were provided in support of the substantial equivalence determination for the G0 Blood Pressure Monitoring System:

The biocompatibility evaluation for the device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The biocompatibility testing includes the following tests:
- Cytotoxicity
- Sensitization
- Irritation

Software validation per FDA guidance and IEC 62304: Medical device software — Software life cycle processes

Safety Testing
- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirement for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
- IEC 80601-2-30: Medical electrical equipment – Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.
- IEC 60601-1-11: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62471: Photobiological safety of lamps and lamp systems

Usability Testing
- IEC 62366-1:2015+AMD1:2020 CSV: Medical devices – Part 1: Application of usability engineering to medical devices.
- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 CSV: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.

Aktiia Init I1 Specific Performance testing
- ISO 81060-2: Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type

Clinical validations of blood pressure per ISO 81060-2:2018 were performed for the G0 Blood Pressure Monitoring System as well as the Aktiia Init I1 (cuff) that is used for calibration purposes. When comparing BP measurements of reference methods to the G0 Blood Pressure Monitoring System and the Aktiia Init I1 (cuff), it was shown that the G0 Blood Pressure Monitoring System and the Aktiia Init I1 achieved the requirements of ISO 81060-2:2018 and accurately displayed blood pressure.

The validation of pulse rate (PR) accuracy for the Aktiia G0 system was conducted as part of the NCT06565780 clinical investigation and compared the device's pulse rate measurements to a reference electrocardiogram (ECG). A total of 85 participants were included in the final dataset, with 1273 simultaneous pulse rate measurements collected under both seated relaxed conditions and during induced blood pressure changes. The primary endpoint required that the root mean square error (RMSE) of pulse rate measurements remain ≤3 beats per minute (bpm) when compared to ECG readings.

The baseline demographic analysis of the 85 subjects included in the study showed a fairly balanced distribution across key categories. Sex distribution consisted of 47% male (40 subjects) and 53% female (45 subjects). The age range spanned from 22 to 59 years, with 49% of participants aged 22-39 years and 51% aged 40-59 years. Racial diversity was represented as follows: 71% White (60 subjects), 18% Black (15 subjects), 8% Asian (7 subjects), and 3% categorized as Other (3 subjects). Ethnicity-wise, 21% of the participants identified as Hispanic (18 subjects), while 79% were Non-Hispanic (67 subjects). This distribution ensured a broad representation of the U.S. population as required by study protocol.

In terms of safety outcomes, only one adverse event (AE) was reported. One participant described experiencing a mild sensation of energy at the device site, though without pain, discomfort, or heat-related complaints. The event was categorized as unexpected, non-serious, and with an unclear relationship to the investigational device or study procedures. The AE resolved completely without residual effects, and no further safety concerns were identified. Overall, the study confirmed the safety and effectiveness of the G0 blood pressure monitoring system in a clinical setting for measuring blood pressure and pulse rate.

The G0 Blood Pressure Monitoring System is as safe and effective as the predicate device. The G0 Blood Pressure Monitoring System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended monitoring use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the G0 Blood Pressure Monitoring System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the G0 Blood Pressure Monitoring System is as safe and effective. Thus, the G0 Blood Pressure Monitoring System is substantially equivalent.