May 6, 2026

Biozen, LLC
Omer Inan
Chief Scientific Officer
7023 N Classen Blvd.
Oklahoma City, Oklahoma 73116

Re: K253152
Trade/Device Name: BP1000 Ultra-Compact Fingertip Blood Pressure Monitor (BP1000)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 26, 2025
Received: September 26, 2025

Dear Omer Inan:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

STEPHEN C. BROWNING -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
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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)*
K253152

Device Name
BP1000 Ultra-Compact Fingertip Blood Pressure Monitor (BP1000)

Indications for Use *(Describe)*
The Biozen BP1000 Ultra-Compact Fingertip Blood Pressure monitor is a digital monitor intended for use in spot check measurements of blood pressure in the adult population using photoplethysmogram and pressure signals obtained from the index finger.

User Population: Adults ages 22-59 who do not have active arrythmias (e.g. Afib), peripheral artery disease, or are pregnant.

Environment of Use: Home

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.

510(k) Summary
Biozen's BP1000 Ultra-Compact Fingertip Blood Pressure Monitor
K253152

Submitter

Biozen, LLC
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Phone: 650-776-9018
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Date Prepared: May 5, 2026

Name of Device: BP1000 Ultra-Compact Fingertip Blood Pressure Monitor (BP1000)

Common or Usual Name: Noninvasive blood pressure measurement system

Classification Name: System, Measurement, Blood-Pressure, Non-Invasive

Regulatory Class: Class II

Product Code: DXN (21 CFR 870.1130)

Predicate Device

Accurate 24 Non-invasive blood pressure monitor, K222658, DXN

Device Description

The BP1000 Ultra-Compact Fingertip Blood Pressure Monitor is a portable, non-invasive medical device intended for the measurement of systolic and diastolic blood pressure in adult patients. The device uses optical sensors (LED and photodiode array), a pressure sensor, a temperature sensor, and an accelerometer to acquire physiological data at the fingertip, with results displayed through a connected mobile application. The BP1000 is designed for home use and is not intended for life-supporting or critical care applications. As such, the system includes built-in safety features and error detection to ensure accurate and reliable operation. Visual indicators on the device and notifications through the mobile application convey operational status, warnings, or error conditions to the user. Only legally marketed accessory items, such as power supplies or USB charging components, should be used with the system. The BP1000 is not intended for continuous monitoring, diagnosis, or as a substitute for professional medical judgment.

Intended Use / Indications for Use

The Biozen BP1000 Ultra-Compact Fingertip Blood Pressure Monitor is a digital monitor intended for use in spot check measurements of blood pressure in the adult population using photoplethysmogram and pressure signals obtained from the index finger.

User Population: Adults ages 22-59 who do not have active arrhythmias (e.g. Afib), peripheral artery disease, or are pregnant.

Environment of Use: Home

Indications for Use Comparison

The BP1000 intended use is substantially equivalent to the predicate device – minor differences are related to the measurement site and exact principle of operation (local pulse wave transit time as compared to oscillometric method). Both are intended to be used as a digital monitor intended for use in spot check measurements of blood pressure. The minor differences in intended use do not have any effect on safety and effectiveness of measurement of BP.

Both the BP1000 and the predicate device use arterial biomechanics principles and optical blood volume pulse (PPG) measurement together with contact force / pressure to enable BP estimation. Additionally, both the subject and the predicate devices are intended for measuring blood pressure in the home environment in an adult population and are labeled as OTC. In other words, the Biozen BP1000 is substantially equivalent to the predicate device.

Technological Comparison

The main differences between the BP1000 and the predicate device are the following: measurement location, means of applying pressure, and means of detection. The difference in measurement location (finger for BP1000 versus wrist for the Accurate 24) does not affect safety or effectiveness because the difference in blood pressure at the wrist versus finger is small for most persons, and for those that might have greater differences due to (1) stiff arteries and associated wave reflections or (2) pressure attenuation due to peripheral vasoconstriction the BP1000 is able to detect such physiological aspects via the Error Checking algorithm. Similarly, the difference in pressure application between the Accurate 24 (which uses a clamp around the wrist to circumferentially apply pressure) and the BP1000 (where pressure is applied linearly by the finger against the device) does not impact the ability to apply such external pressure to the arteries in the volume of tissue. Moreover, the theoretical basis for such linear application of pressure is rich in the field of tonometry. Finally, while the Accurate 24 uses the Bramwell Hill and Moens Korteweg equations to translate local pulse wave transit time measurements to a BP estimate, together with the concurrent extraction of luminal area changes in the arteries via PPG sensing, the BP1000 uses the ubiquitous methodology of oscillometry, also based on the concurrent extraction of luminal area changes in the arteries via PPG. Thus, the means of detection difference in the BP1000 compared to the Accurate 24 does not impact safety and effectiveness of the device.

In summary, the predicate device is legally marketed and Biozen BP1000 has the same intended use as the predicate device, digital monitor intended for use in spot check measurements of blood pressure. Furthermore, any differences in the indication statement do not affect safety and effectiveness of the device. The technological characteristics are comparable as both use similar signals (PPG and contact force / pressure), and both use well established arterial biomechanics principles to measure BP. Thus, Biozen BP1000 is substantially equivalent to the predicate device as described in Table I.

Non-Clinical Tests Summary

Non-clinical tests were conducted to verify that the subject device met all design specifications. The test results demonstrated that the subject device complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
- IEC 62471 First edition 2006-07
- ANSI/AAMI/ISO 14971: 2019
- ANSI/AAMI/ISO 10993-1: 2018
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
- ISO 81060-2 Third edition 2018-11 [Including AMD1:2020]
- IEC TS 60601-4-2 Edition 1.0 2024-03
- USEMCSC C63.27-2021

Human factors usability study was conducted to demonstrate the device is safe, effective, and usable; and that differences from the predicate do not introduce any new and unacceptable risk.

Software Design, Verification, and Validation was conducted in accordance with ISO 62304.

Table I. Substantial Equivalence Comparison Table

Parameter	Biozen BP1000	Accurate 24
Classification and Code	DXN – Noninvasive blood pressure measurement system	DXN – Noninvasive blood pressure measurement system
Indications for Use	The Biozen BP1000 Ultra-Compact Fingertip Blood Pressure Monitor is a digital monitor intended for use in spot check measurements of blood pressure in the adult population using photoplethysmogram and pressure signals obtained from the index finger. User Population: Adults ages 22-59 who do not have active arrhythmias (e.g. Afib), peripheral artery disease, or are pregnant. Environment of Use: Home	The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patient (age 20–70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI < 40. Intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use. Measurement results store in the device locally. Measures BP based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.
OTC	Yes	Yes
Patient Population	Adult	Adult
Environment of Use	Home	Home, hospitals, clinics, long-term care
Measurements Made	SBP and DBP	SBP, DBP, Pulse rate
Pressure Range	0–299 mmHg	0–299 mmHg
Principle of Operation	Oscillometric	PWTT-based estimation of BP using arterial biomechanics principles

Means of Applying Pressure	Finger pressing	Clamp around wrist
Means of Detection	Optical (PPG)	Optical (PPG)

Clinical Performance Testing

I. General Description of the Pivotal Study

The study was conducted in accordance with ISO:81060-2. Specifically, ISO:81060-2 calls for at least 85 people and 255 paired measurements to evaluate the accuracy of any device under test (DUT). The paired measurements are obtained by combining dual observer auscultation as the reference before and after each DUT measurement. In addition to ISO:81060-2, the IEEE 1708a:2019 standard was partially applied, specifically with regards to including two confounding factors studies in addition to the general study: one for skin tone, and one for BMI. Lastly, the study was conducted at three distinct geographical locations.

II. General and Confounding Studies

To evaluate the accuracy of BP1000 on the representative United States population, a general study (G01) together with two confounding studies have been conducted. The two confounding studies are: (G02) Fitzpatrick Skin Type V-VI, and (G03) BMI Obesity Grade I-II. Each of these sub studies included 88 participants aged between 22-59 years old, who did not have compromised circulation, or arrhythmias (e.g., Afib), or were pregnant, with the demographic distribution (age, gender, BMI, and Fitzpatrick skin tone) outlined in ISO 81060-2:2018/AMD 1:2020 and partially in IEEE 1708a:2019. The blood pressure distribution for all subjects adhered to ISO 81060-2:2018/AMD 1:2020 for each sub study.

III. Statistical Analysis

The overall blood pressure accuracy results against acceptance criteria are presented in Table II.

Table II. Blood pressure accuracy of all measurements included in the data analysis for all studies.

		General Study (G01)	Fitzpatrick 5&6 (G02)	BMI Obesity I&II Study (G03)
Systolic Blood Pressure Criteria				
Criterion 1: Mean of Systolic Blood Pressure Differences	Criterion	within or equal to ±5 mmHg	within or equal to ±5 mmHg	within or equal to ±5 mmHg
	BP1000	**-0.9 mmHg**	**0.1 mmHg**	**-1.1 mmHg**
	Status	PASS	PASS	PASS
Criterion 1: Standard Deviation of Systolic Blood Pressure Differences	Criterion	≤ 8 mmHg	≤ 8 mmHg	≤ 8 mmHg
	BP1000	**7.49 mmHg**	**7.37 mmHg**	**7.27 mmHg**
	Status	PASS	PASS	PASS
Criterion 2: Standard Deviation of Systolic Blood Pressure Differences	Criterion	≤ 6.88 mmHg	≤ 6.95 mmHg	≤ 6.86 mmHg
	BP1000	**6.66 mmHg**	**6.61 mmHg**	**6.48 mmHg**
	Status	PASS	PASS	PASS
Diastolic Blood Pressure Criteria				

Criterion 1: Mean of Diastolic Blood Pressure Differences	Criterion	within or equal to ±5 mmHg	within or equal to ±5 mmHg	within or equal to ±5 mmHg
	BP1000	**-1.4 mmHg**	**-2.0 mmHg**	**-1.5 mmHg**
	Status	PASS	PASS	PASS
Criterion 1: Standard Deviation of Diastolic Blood Pressure Differences	Criterion	≤ 8 mmHg	≤ 8 mmHg	≤ 8 mmHg
	BP1000	**7.01 mmHg**	**6.5 mmHg**	**6.55 mmHg**
	Status	PASS	PASS	PASS
Criterion 2: Standard Deviation of Diastolic Blood Pressure Differences	Criterion	≤ 6.80 mmHg	≤ 6.65 mmHg	≤ 6.78 mmHg
	BP1000	**6.59 mmHg**	**6.09 mmHg**	**6.16 mmHg**
	Status	PASS	PASS	PASS

IV. Conclusion

The accuracy of Biozen BP1000 was compared against dual observer auscultation in accordance with ISO:81060-2. It was demonstrated that the blood pressure accuracy of Biozen BP1000 met all requirements of ISO:81060-2 for all sub studies: General Study (G01), Fitzpatrick 5&6 Study (G02), and BMI Obesity I&II Study (G03).

Based on the results of Non-Clinical and Clinical testing, we conclude that the BP1000 device is as safe and effective as the predicate device, and the differences present no new patient risks. Based on the clinical performance as documented in the pivotal clinical study, the Biozen BP1000 Ultra-Compact Fingertip Blood Pressure Monitor has a safety and effectiveness profile that is similar to the predicate device.

Human Factors Validation

A summative human factors (HF) validation study was conducted to demonstrate that the BP1000 can be used safely and effectively by the intended user population in the intended use environment. The study followed FDA's recommended two-step approach for over-the-counter (OTC) device validation, comprising a Self-Selection Assessment followed by Performance Testing.

All 19 participants in the summative HF validation study self-selected correctly, with no use errors, close calls, or difficulties. Among the 16 intended-user participants in Performance Testing, the medication critical task was passed without error. The healthcare-provider-contact critical task was passed.

The HF validation supports the conclusion that the BP1000 can be used safely and effectively by intended users in the intended use environment, and that any differences from the predicate device do not introduce new use-related risks.

Bench Testing

To support the device performance under expected conditions, two bench tests were performed: low perfusion, and packet loss testing.

I. Low Perfusion Testing

An unpowered confirmatory study was performed to validate the ability of the BP1000 to provide an error in participants with very low perfusion index. In this confirmatory perfusion study, the BP1000 detected errors in all 20 participants and thus the sensitivity was 100%. Therefore, the device correctly detected poor perfusion and outputted an error message every time.

II. Packet Drop Testing
A packet drop testing was performed in accordance with IEC 60601-1-2 to investigate the BP1000 blood pressure algorithm robustness under simulated Bluetooth Low Energy (BLE) packet drop conditions. The BP1000 and its algorithm meet ISO 81060-2 accuracy criteria even under the worst-case scenario. Across all tested packets drop ratios, the worst-case scenario errors are also below the prespecified thresholds. Hence, the algorithm is verified as robust for clinical use in real-world environments.

Predetermined Change Control Plan

This device has been cleared with a Predetermined Change Control Plan (PCCP). Future modifications to its algorithm will be made in accordance with this PCCP. The PCCP outlines a description of the planned modifications, the protocol to implement and validate, and the procedures to deploy and rollback. This PCCP ensures the continued safety and effectiveness of the device, mitigating the risks of the modifications leading to changes in the device's performance specifications directly associated with the indications for use of the device. Users will be informed of each update through revised labeling, release notes, or other appropriate communication channels.

The number of subjects required for validation for the below modifications is a dataset of n=85 subjects, with sufficient representation of each demographic criteria (age, gender, BMI, Fitzpatrick skin tone) and blood pressure distribution such that subgroup analysis can be performed.

A summary is provided in the table below.

Table III. Proposed Modifications of BP1000 under the PCCP

Modification	**Rationale**	**Testing Method / Acceptance Criteria**
Error Checking Algorithm	Re-training of the Error Checking Algorithm increases the benefits to the user by improving successful measurement rates, reducing time-to-result, increasing device adherence and users' familiarity with the device, and ultimately ensuring higher data integrity for the user.	The algorithm will be re-trained and validated using a sequestered test set (n=85 subjects). Performance will be assessed via comparative analysis against the cleared version to ensure it meets the predetermined performance criteria as well as the criteria specified in ISO 81060-2:2018. Specifically, the acceptance criteria will be: (1) equivalent (0% non-inferiority) or better sensitivity and performance under ISO 81060-2:2018 compared to the cleared device, (2) 10% improvement in specificity, and (3) blood pressure accuracy still meeting both Criterion 1 and Criterion 2 of ISO 81060-2:2018.

Blood Pressure Determination Algorithm	The improved accuracy of the Blood Pressure Determination Algorithm will give users more confidence in the device and enhance device adherence and similarly improve device usage and data integrity.	The algorithm will be re-trained and validated using a sequestered test set (n=85 subjects). Performance will be assessed via comparative analysis against the cleared version to ensure it meets the predetermined performance criteria as well as the criteria specified in ISO 81060-2:2018. Specifically, the acceptance criteria will be: (1) equivalent (0% non-inferiority) or better performance under ISO 81060-2:2018 compared to the cleared device, (2) improvement in standard deviation of blood pressure error by a minimum of 0.3 mmHg, and (3) blood pressure accuracy still meeting both Criterion 1 and Criterion 2 of ISO81060-2:2018.