August 13, 2026

Wellvii, Inc.
Mark Khachaturian
CEO
4521 Pga Blvd., Pmb 341
Palm Beach Gardens, Florida 33418

Re: K261061
Trade/Device Name: BP Go
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 31, 2026
Received: March 31, 2026

Dear Mark Khachaturian:

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 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

CDR 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.

510(k) Number *(if known)*
K261061

Device Name
BP Go

Indications for Use *(Describe)*
The Wellvii Inc. BP Go™ is a device designed for spot measurements with recorded results of non-invasive blood pressure (NIBP), and pulse rate from the base of the left index finger.

This device is intended for use by persons aged 18 years and older only with a left index finger circumference between 5.1 [cm] to 8.0 [cm].

This device is not intended for use in patients with irregular heart rhythms, including atrial fibrillation, patients that are pregnant, or patients with poor peripheral perfusion/peripheral vascular disease.

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.

1. SUBMITTER INFORMATION

Applicant:	Wellvii Inc
Contact:	Mark Khachaturian
Phone:	+1 561 559 2945
Email:	markk@wellvii.com
Address	4521 PGA Blvd, PMB 341 Palm Beach Gardens, FL 33418

2. CORRESPONDENT INFORMATION

Contact:	Mark Khachaturian
Title:	CEO
Firm:	Wellvii Inc.
Phone:	+1 561 559 2945
Email:	markk@wellvii.com

DATE PREPARED: AUGUST 11, 2026

3. DEVICE INFORMATION

Device Name:	BP Go
Common Name:	Noninvasive blood pressure measurement system
Regulation Number:	21 CFR 870.1130
Regulation Name:	Noninvasive blood pressure measurement system
Product Code:	DXN
Regulatory Class:	Class II

4. PREDICATE DEVICE INFORMATION

Primary Predicate Device Name:	CalHealth Finger Blood Pressure Monitor, MDMouse
510(k) Number:	K081924
Manufacturer:	CalHealth, Inc.

5. DEVICE DESCRIPTION

BP Go is a non-invasive device for spot-checking blood pressure.

The BP Go uses the oscillometric method to measure blood pressure from the base of the finger as described in the steps below.

1. The user inserts their finger in the cuff and tightens the strap to hold the finger steady.
2. The cuff inflates to 230 [mmHg].
3. The cuff deflates to 30 [mmHg].
4. Using the oscillometric method, the systolic and diastolic blood pressure are calculated. The oscillometric method of measurement relies on the principle that blood flow through an artery creates oscillations in the arterial wall. The finger blood pressure cuff detects these oscillations, which manifest as small pulsations in the cuff pressure. As the cuff gradually deflates from above systolic pressure, the monitor records the changes in pressure amplitude. When the pulse overcomes the occlusion in the artery, the amplitude sharply increases. As the cuff pressure continues to drop, the pulsations grow stronger, peaking at the mean pressure, before gradually fading.

The pulse rate is calculated from the peak to peak of the oscillometric signal.1

6. INDICATIONS FOR USE

The Wellvii Inc. BP Go™ is a device designed for spot measurements with recorded results of non-invasive blood pressure (NIBP), and pulse rate from the base of the left index finger.

This device is intended for use by persons aged 18 years and older only with a left index finger circumference between 5.1 [cm] to 8.0 [cm].

This device is not intended for use in patients with irregular heart rhythms, including atrial fibrillation, patients that are pregnant, or patients with poor peripheral perfusion/peripheral vascular disease.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Other than the change in finger circumference, form factor and user interface as noted in Table 1, the subject device is equivalent to the referenced predicate device.

Table 1: Technological Comparison to Predicate Devices

Product	**Proposed Device:** **BP Go**	**Predicate Device:** **MDMouse [K081924]**
General Characteristics		
Manufacturer	Wellvii Inc.	CalHealth, Inc.
Regulation Number	21 CFR 870.1130	21 CFR 870.1130

Product	**Proposed Device:** **BP Go**	**Predicate Device:** **MDMouse [K081924]**
	Noninvasive BP measurement system	Noninvasive BP measurement system
Class and Product Code	Class II, DXN	Class II, DXN
Patient Population	Adults aged 18 years and older	Adults aged 18 years and older
Parameters Measured	Blood Pressure, Pulse Rate	Blood Pressure, Pulse Rate
Use Location	Clinical Setting, Home Use (OTC)	Home Use (OTC)
Form Factor	Handheld stand-alone Device	Computer mouse with integrated BP cuff
Power Source	Rechargeable 3.7 V lithium-polymer battery (with low-battery indicator)	USB power from PC (5V)
Display	1.3 [in] 240 x 240 pixel; integrated color display	Displayed via PC software
Data Storage/ Connectivity	None	PC-based Storage; Email/ Online data export
Blood Pressure		
Principle of Operation	The finger cuff occludes blood flow and uses the oscillometric principle to estimate systolic and diastolic.	The finger cuff occludes blood flow and uses the oscillometric principle to estimate systolic and diastolic.
Measurement site	Left index finger	Left index finger
Measurement type	Spot-check	Spot-check
Measurement Initiation	Press device Start button	Press ENTER on PC keyboard (software-based)
Finger cuff	175º finger cuff which fills with air on the underside of the finger	360º finger cuff
Finger Circumference	5.1 to 8.0 [cm]	3.7–8.8 [cm]
Measurement Range	Systolic (SYS): 60 mmHg to 230 mmHg Diastolic (DIA): 40 mmHg to 130 mmHg	SYS/DIA: 55 - 200mmHg
Accuracy	Systolic MDV: 2.11 mmHg STD: ±7.32 mmHg Diastolic MDV: 1.22 mmHg STD: ±6.36 mmHg	±3 mmHg
Over Pressure Limit	Active if cuff pressure exceeds 300 mmHg.	No explicit over-pressure limit specified

Product	Proposed Device: BP Go	Predicate Device: MDMouse [K081924]
Pulse Rate		
Principle of Operation	Pulse Rate (PR) Peak Detection of Oscillometric signal	Pulse Rate (PR) Peak Detection of Oscillometric signal
Measurement Range	40-140 bpm*	40-200 bpm
Accuracy	± 1.23 bpm over the range of 51 to 102 bpm	± 5% of reading value

* Clinical validation was performed from 51 to 102 bpm while bench testing was performed over the entire range of 40 to 140 bpm.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

No biocompatibility testing was conducted. The materials of construction of the BP Go device are considered in common use for other consumer products with similar nature of contact, and in such cases, ISO 10993-1 states that no further biological evaluation is needed. Furthermore, a majority of the materials are listed in the FDA guidance as presenting a low biocompatibility risk, further supporting the conclusion that no additional evaluation was required to ensure the user safety.

Electrical Safety

The following electrical safety testing was conducted under the ASCA scheme:

- ANSI/AAMI ES60601-1:2005 (R) 2012/A1:2012/C1:2009 (R) 2012/A2:2010 (R) 2012 (consolidated edition, including Amd.2:2021), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD, including Amendment 2:2021)

Clinical

Clinical trials were completed to validate the clinical accuracy and functionality of the proposed device. The study was conducted in accordance with ISO 81060-2:2018, *Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type*. The study population consisted of 85 qualified subjects ranging from 18 to 85 years of age. The subjects were 54% male and 46% female with finger sizes ranges from 5.1 to 8.4 cm.

Table 2 summarizes the study results. The BP Go met the accuracy performance requirements of the standard.

Table 2: Blood Pressure and Pulse Rate Accuracy Results

	Criterion 1		Criterion 2
	Mean Error	**Standard Deviation**	**Standard Deviation (Mean permissible from Table 1)**
Acceptance Criteria	≤ 5.0 mmHg	≤ 8.0 mmHg	Systolic ≤6.62 (ME 2.1) Diastolic ≤6.84 (ME 1.2)
Systolic	2.22	7.32	6.57
Diastolic	1.22	6.36	5.60

The pulse rate accuracy met the acceptance criteria with an ARMS = 1.23 bpm over the tested range of 51 to 102 bpm. The full pulse rate range of 40 to 140 bpm was tested on the bench and was shown to be accurate to < ± 1 [bpm].

Electromagnetic Compatibility (EMC)

The following electromagnetic compatibility (EMC) testing was conducted under the ASCA scheme:

- IEC 60601-1-2:2020/Ed.4.1, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- ANSI/AAMI/IEC 60601-1-2:2014 (including Amd.1:2021), *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

Software

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Verification of the BP Go was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

Performance Testing

The following performance testing was conducted under the ASCA scheme:

- IEC 60601-1-6:2020/Ed.3.2, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
- IEC 60601-1-11: 2020/Ed.2.1, *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 80601-2-30:2018/Ed.2: *Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers*

8. CONCLUSION

The results of the performance testing described above demonstrate that the BP Go performs equivalently as compared to the predicate device and supports a determination of substantial equivalence.