June 26, 2026

Biotracker, LLC
% Jorge Millan
Regulatory Affairs Director
Sigma Biomedical
490 Sawgrass Corporate Pkwy., Suite 130
Sunrise, Florida 33325

Re: K253306
Trade/Device Name: BioTracker 2.0
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II
Product Code: MWI, DQA, DXN
Dated: September 29, 2025
Received: September 29, 2025

Dear Jorge Millan:

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,

Jackson Hair -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253306

Device Name
Biotracker 2.0

Indications for Use *(Describe)*
BioTracker 2.0 is software intended to acquire, display, store, organize, and report physiological data obtained from compatible legally marketed physiological acquisition devices for review by licensed healthcare professionals.
The software acquires physiological measurements including oxygen saturation (SpO_2), pulse rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure (MAP).
The software performs mathematical analysis of the acquired physiological measurements and derived pulse waveform data to calculate the following parameters:
• Ankle-Brachial Index (ABI) (right and left)
• Root Mean Square of Successive Differences (RMSSD)
• Standard Deviation of Normal-to-Normal Intervals (SDNN)
• Percentage of Successive NN Intervals Differing by More Than 50 ms (pNN50)
• Low Frequency/High Frequency Ratio (LF/HF)
• Reflection Index (RI)
• Pulse Wave Amplitude Ratio (PWAR)
• Stiffness Index (SI)
Each calculated parameter is displayed individually together with its corresponding unit of measure. BioTracker 2.0 performs mathematical analysis and presentation of physiological data only. The software does not provide diagnostic interpretations, disease classification, patient risk scores, comparative indicators, alarms, treatment recommendations, or aggregated clinical assessments. Interpretation of the reported physiological measurements and calculated parameters is the responsibility of the licensed healthcare professional.
BioTracker 2.0 is intended for spot-check physiological assessments only. It is not intended for continuous physiological monitoring, real-time patient monitoring, life-support applications, or physiological alarm generation.
BioTracker 2.0 is intended for use in primary care practices, family medicine practices, internal medicine practices, outpatient physician offices, and outpatient healthcare clinics.
BioTracker 2.0 is intended for use by licensed healthcare professionals on adult patients 18 years of age or older.
Prescription Use Only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Submitter Information

Submitter	BioTracker LLC
Contact:	Jorge Millan, PhD
Telephone number	+1 786 416 5587
E-mail	jmillan@sigmabiomedical.com
Date prepared:	June 26, 2026

Device Name

Trade/Proprietary Name:	BioTracker 2.0
Regulation Number:	21 CFR 870.2300, 21 CFR 870.1130
Regulation Name:	Cardiac Monitor
Product Code:	MWI, DQA, DXN
Class	II
Panel	Cardiovascular

Primary Predicate Device

Predicate Device:	Oxi-W System
Sponsor	LD Technology, LLC
510(K)	K200141
Regulation Number:	21 CFR 870.2300,
Regulation Name:	Cardiac Monitor (including cardiotachometer and rate alarm)
Product Code:	MWI, DQA
Class	II
Panel	Cardiovascular

Secondary Predicate Device

Predicate Device:	Microlife Upper Arm Automatic Digital Blood Pressure Monitor, WatchBP Office Central (TWIN200 CBP)
Sponsor	Microlife Intellectual Property GmbH
510(K)	K171937
Regulation Number:	21 CFR 870.1130
Regulation Name:	Noninvasive Blood Pressure Measurement System — Microlife

Product Code:	DXN
Class	II
Panel	Cardiovascular

Indications for Use:

BioTracker 2.0 is software intended to acquire, display, store, organize, and report physiological data obtained from compatible legally marketed physiological acquisition devices for review by licensed healthcare professionals. The software acquires physiological measurements including oxygen saturation (SpO_2), pulse rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure (MAP). The software performs mathematical analysis of the acquired physiological measurements and derived pulse waveform data to calculate the following parameters:

- Ankle-Brachial Index (ABI) (right and left)
- Root Mean Square of Successive Differences (RMSSD)
- Standard Deviation of Normal-to-Normal Intervals (SDNN)
- Percentage of Successive NN Intervals Differing by More Than 50 ms (pNN50)
- Low Frequency/High Frequency Ratio (LF/HF)
- Reflection Index (RI)
- Pulse Wave Amplitude Ratio (PWAR)
- Stiffness Index (SI)

Each calculated parameter is displayed individually together with its corresponding unit of measure. BioTracker 2.0 performs mathematical analysis and presentation of physiological data only. The software does not provide diagnostic interpretations, disease classification, patient risk scores, comparative indicators, alarms, treatment recommendations, or aggregated clinical assessments. Interpretation of the reported physiological measurements and calculated parameters is the responsibility of the licensed healthcare professional.

BioTracker 2.0 is intended for spot-check physiological assessments only. It is not intended for continuous physiological monitoring, real-time patient monitoring, life-support applications, or physiological alarm generation. BioTracker 2.0 is intended for use in primary care practices, family medicine practices, internal medicine practices, outpatient physician offices, and outpatient healthcare clinics. BioTracker 2.0 is intended for use by licensed healthcare professionals on adult patients 18 years of age or older.

Prescription Use Only.

Device Description:

The BioTracker Software connects to compatible biomedical devices including a pulse oximeter and blood pressure monitor. These devices collect physiological signals which are transmitted to the BioTracker software. The software processes these inputs using validated algorithms to calculate parameters such as HRV and ABI.

Processed data is stored in a local database linked to individual patient records under a HIPAA-compliant system. The system displays results and generates structured reports including numerical values and waveform analysis. Each output is presented individually with its unit; the software assigns no qualitative category, score, comparative indicator, or interpretive classification, and does not combine, average, or

aggregate measurements. Reports can be printed, stored, or exported locally (PDF). The user interface guides the clinician through calibration, test execution, and reporting.

Non-Clinical Data:

Non-clinical product evaluation to demonstrate safety and effectiveness was conducted. Non-clinical testing includes:

- Risk Management: ISO 14971:2019
- Software verification and validation testing were conducted on the BioTracker 2.0 system 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." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software would lead to a delayed delivery of appropriate medical care. Documentation includes level of concern, software requirements and specifications, design architecture, risk analysis and software validation and verification.
- Performance Testing was conducted to verify performance as per requirements and specifications.

Predicate Devices

BioTracker 2.0 is comparable with and substantially equivalent to the primary predicate, Oxi-W System, cleared under K200141, with the Microlife Upper Arm Automatic Digital Blood Pressure Monitor (WatchBP Office Central, TWIN200 CBP), cleared under K171937, as a secondary predicate supporting the Ankle-Brachial Index output.

Technical Characteristics Comparison:
The basic and main technical features of the subject device are similar as the predicated device.

Feature Comparison:
Subject device has similar features and functionality as the predicate device as shown in the following comparison table:

Characteristic	**New Device: BioTracker 2.0**	Predicate Device: Oxi-W System (K200141)	Microlife WatchBP Office Central (K171937)	**Comparison**
Manufacturer	BioTracker LLC	LD Technology (Oxi-W System);	Microlife IP GmbH (Microlife)	N/A
Device Name,Model	BioTracker 2.0	Oxi-W System;	WatchBP Office Central (TWIN200 CBP)	N/A
ClassificationName	Cardiac Monitor Noninvasive BP Measurement System	Cardiac Monitor	Noninvasive BP Measurement System	Different
Regulatory Class	Class II	Class II		Similar
Product Code	MWI, DQA, DXN	MWI, DQA	DXN	Different

Characteristic	**New Device: BioTracker 2.0**	Predicate Device: Oxi-W System (K200141)	Microlife WatchBP Office Central (K171937)	**Comparison**
RegulationNumber	21 CFR 880.5400; 21 CFR 870.1130; 21 CFR 870.2700; 21 CFR 882.1540; 21 CFR 862.2100	21 CFR 870.2300	21 CFR 870.1130	Different
510(K) Number	K253306	K200141	K171937	N/A
Prescription/OTC	Prescription	Prescription	Prescription	Similar
Compliance with voluntary standards	Yes	Yes	Yes	Similar
Indications for use	BioTracker 2.0 is software intended to acquire, display, store, organize, and report physiological data obtained from compatible legally marketed physiological acquisition devices for review by licensed healthcare professionals. The software acquires physiological measurements including oxygen saturation (SpO_2), pulse rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure (MAP). The software performs mathematical analysis of the acquired physiological measurements and derived pulse waveform data to calculate the following parameters: • Ankle-Brachial Index (ABI) (right and left) • Root Mean Square of Successive Differences (RMSSD) • Standard Deviation of Normal-to-Normal Intervals (SDNN) • Percentage of Successive NN Intervals Differing by	Oxi-W system is intended for use: To spot check or monitor Oxygen saturation of arterial hemoglobin (SpO2%) and pulse rate. To analyze the pulse waveform (Photoplethysmography or PTG) provided by the oximeter. It only provides mathematical analysis of the input of the PTG using the first and second derivatives of the PTG values related to the microvascular condition. To analyze the basic rhythms of the NN or RR intervals in heart rate from the PTG, both in the time domain and in the frequency domain (short time 5 minutes). It only provides mathematical analysis of the heart rate variability values related to the autonomic nervous system function. The system only provides mathematical analysis of input PTG values. It is practitioner to make proper judgement based on these values. The software provides a visual alarm for the values of the heart rate and/or SpO2 percent out of the normal range and for the bad quality signal transmission. The data are stored in PC in the Backup system of the Oxi-W software. The device is intended use only	The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Central (TWIN200 CBP) is a device intended to measure the systolic and diastolic blood pressure, pulse rate, Mean Arterial Pressure (MAP), anklearm blood pressure and calculates Pulse Pressure (PP) and Ankle Brachial Index (ABI) of an adult individual with arm circumference sizes ranging from 22-42 cm and ankle circumference sizes ranging from 22-32 cm. It uses a non-invasive oscillometric technique using one (single arm) or two (dual arm measurement) inflatable cuffs wrapped around the upper arms and one inflatable cuff wrapped around the ankle (ABI). The device provides aortic blood pressure parameters, includes central systolic blood	Similar (numeric physiological outputs from cleared devices)

Characteristic	**New Device: BioTracker 2.0**	Predicate Device: Oxi-W System (K200141)	Microlife WatchBP Office Central (K171937)	**Comparison**
	More Than 50 ms (pNN50) • Low Frequency/High Frequency Ratio (LF/HF) • Reflection Index (RI) • Pulse Wave Amplitude Ratio (PWAR) • Stiffness Index (SI) Each calculated parameter is displayed individually together with its corresponding unit of measure. BioTracker 2.0 performs mathematical analysis and presentation of physiological data only. The software does not provide diagnostic interpretations, disease classification, patient risk scores, comparative indicators, alarms, treatment recommendations, or aggregated clinical assessments. Interpretation of the reported physiological measurements and calculated parameters is the responsibility of the licensed healthcare professional. BioTracker 2.0 is intended for spot-check physiological assessments only. It is not intended for continuous physiological monitoring, real-time patient monitoring, life-support applications, or physiological alarm generation. BioTracker 2.0 is intended for use in primary care practices, family medicine practices, internal medicine practices,	for adult subjects (> 20 years old) This Oximeter is intended to be used in spot-checking (5 minutes). The device is intended for use in licensed practitioner's office This device is no intended to be used at home, in hospital or out-of-hospital transport The device is not intended for use in support life and not for continuously monitoring The system will be used by practitioner.	pressure (cSBP), central pulse pressure (cPP) and central diastolic pressure (cDBP), non-invasively through the use of a brachial cuff. The device detects the appearance of atrial fibrillation during measurement and gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected. The blood pressure monitor is an automated digital professional clinical device for measuring blood pressure in upper arm and ankle in adults.	

Characteristic	**New Device: BioTracker 2.0**	Predicate Device: Oxi-W System (K200141)	Microlife WatchBP Office Central (K171937)	**Comparison**
	outpatient physician offices, and outpatient healthcare clinics. BioTracker 2.0 is intended for use by licensed healthcare professionals on adult patients 18 years of age or older. Prescription Use Only.			
Target population	Adult patients	Adult subjects (>20 years) — Oxi-W		Similar
Measured and calculated variables	**Measured:** SpO_2, NIBP (SBP/DBP/MAP), Pulse Rate/Heart Rate **Calculated:** HRV, ABI and Pulse Wave Parameters	SpO_2 Pulse rate / HR Plethysmography (PPG) HRV (RMSSD, SDNN, pNN50, LF/HF)	Systolic Blood Pressure (SBP) Diastolic Blood Pressure (DBP) Pulse Rate (PR) Ankle Blood Pressure Brachial Blood Pressure	Similar
Software / firmware / microprocessor control	Yes	Yes	Yes	Similar
User Interface	Windows desktop graphical UI; menus/tabs/forms; mouse/keyboard input; report preview & export.	PC-based graphical UI with equivalent navigation and report functions.	The device can be connected to a personal computer (PC) running the WatchBP Analyzer Office software.	Similar
Display	PC Display	PC Display	The measured patient data can be transferred from the blood pressure monitor to the PC by means of a USB cable connection.	Similar
Operator	It can be operated by trained healthcare personnel; no special technical training beyond general computer use is required.	Can be operated by trained healthcare personnel with similar ease of use.	The device is for hospital use only.	Similar
Menu / Settings	Dedicated graphical user interface (GUI) within the application, providing access to user management, physician information, test initiation, and configurable reporting/export	Special GUI within the application with equivalent functionality for patient data management and reporting.	Special GUI within the application with equivalent functionality for patient data management and reporting.	Similar

Characteristic	New Device: BioTracker 2.0	Predicate Device: Oxi-W System (K200141)	Microlife WatchBP Office Central (K171937)	Comparison
	options.			

Evaluation of similarities and differences:

- BioTracker 2.0 and the Oxi-W System (primary predicate) have similar intended use, functionality, and operating principles. Both are standalone PC-based software applications that acquire, process, display, and store physiological data obtained from compatible FDA-cleared measurement devices, and both perform deterministic mathematical analysis of the photoplethysmographic (PPG) waveform to produce pulse-waveform-derived indices and heart-rate-variability (HRV) metrics. In both systems, the software provides healthcare professionals with numeric values such as oxygen saturation (SpO_2), pulse rate, HRV metrics, and pulse-waveform-derived indices, without independent diagnosis or interpretation. The Microlife WatchBP Office Central (secondary predicate) supports the Ankle-Brachial Index (ABI) output, which it calculates and validates per ISO 81060-2. Non-clinical performance testing and usability validation confirm that safety and effectiveness are comparable.

- Differences between BioTracker 2.0 and the Oxi-W System relate mainly to the graphical user interface and the framing of outputs. Unlike the Oxi-W System, BioTracker 2.0 provides no physiological alarms and presents outputs only as numeric values, without relating them to autonomic-nervous-system function or microvascular condition; BioTracker 2.0 is therefore a narrower and more conservative device. These differences do not raise any new questions of safety or effectiveness. Both systems rely exclusively on FDA-cleared acquisition devices, ensuring that device-level performance and safety have already been established.

Conclusion:

Based on the comparison of intended use, technological characteristics, performance, and safety, the BioTracker 2.0 Software is substantially equivalent to the primary predicate device, Oxi-W System (K200141), with the Microlife WatchBP Office Central (K171937) as a secondary predicate supporting the Ankle-Brachial Index output. BioTracker 2.0 relies on FDA-cleared accessories (Pulse Oximeter CMS50E, 510(k) K090671, and Blood Pressure Monitor BP2/BP2A, 510(k) K193348) to obtain physiological data.

The differences identified, including updates in operating system compatibility, improvements in the graphical user interface, and expanded reporting capabilities, do not raise new questions of safety or effectiveness. These differences represent software usability and performance enhancements that have been verified and validated, while maintaining the same technological principles as the predicate device.

Accordingly, the BioTracker 2.0 Software demonstrates equivalent safety and effectiveness to the predicate device, and no new risks are introduced.