



May 16, 2025

iOrbit Digital Technologies Private Limited
Sandeep Zende
Principal Staff Member - Regulatory
4th floor, Nagamma Devi Complex, Site No. 22,
Survey No. 81/2E, Bannerghatta Main Road
Bangalore, Karnataka 560076
India

Re: K243837

Trade/Device Name: iBSM

Regulation Number: 21 CFR 870.2910

Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver

Regulatory Class: Class II

Product Code: DRG, MWI, FLL, DQA, MWJ, BZQ, KMI, DXN

Dated: December 4, 2024

Received: December 13, 2024

Dear Sandeep Zende:

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,


Stephen C. Browning -S

LCDR Stephen Browning

Assistant Director

Division of Cardiac Electrophysiology,

Diagnosics, and Monitoring Devices

Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K243837

Device Name
iBSM

Indications for Use (Describe)

iBSM is a wireless monitoring system intended for the display of electrocardiography (ECG) waveform, heart rate measurements, respiratory rate measurement and waveform, functional oxygen saturation of arterial hemoglobin (SpO₂), activity, body position, fall detection, skin temperature and Blood Pressure parameter measurements by qualified healthcare professionals in healthcare settings. iBSM continuously monitors the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system provides visual notification when the patient's position has not changed from a preset time threshold.

The iBSM device is intended for use on general care patients who are 18 years of age or older as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment.

The iBSM device is not intended for use on critical care patients.

The iBSM BP cuff is not intended for subjects that are considered special populations.

The iBSM device is indicated for monitoring ECG waveforms and heart rate on non-ambulatory patients.

The iBSM device is intended to be used in wards and patient rooms in professional healthcare facility environment hospital settings.

The iBSM device is not intended to be used in Home environment or special environment.

The iBSM device is not intended to be used in an ambulatory environment for noninvasive blood pressure, respiratory rate and SpO₂ measurement parameters.

The iBSM device is not intended to monitor or measure respiratory rate, SpO₂, or noninvasive blood pressure while the patient undergoes significant motion or is active.

The iBSM device is not intended to be used in the ICU/CCU or Surgery/OT rooms

iBSM is compatible with third-party, FDA cleared devices such as ANNE Chest from Sibel Health Inc, for ECG, HR, RR, body position and skin temperature measurements; and ANNE Limb from Sibel Health Inc. for SpO₂ and skin temperature measurements.

iBSM is compatible with third-party, FDA-cleared BP devices such as BP2A from Shenzhen Viatom, for non-invasive blood pressure measurements.

The iBSM device communicates with an external server for patient data communication and storage.

The iBSM device includes the ability to notify healthcare professionals when physiological data fall outside selected parameters with the use of audio and visual alarms.

The iBSM chest sensor is not intended to be used to provide diagnostic or interpretive statements to either the patient or the clinician. The iBSM chest sensor is NOT intended to be used on critical care patients and is not a remote diagnostic device. The iBSM chest sensor is NOT intended for use on patients with implanted pacemakers. The iBSM Chest sensor is NOT intended for use on patients with known allergies, or hypersensitivities to, adhesives or nickel. The iBSM Chest Sensor is NOT intended for patients with significant cardiorespiratory disease including patients that are oxygen dependent. The iBSM Chest Sensor is NOT intended for patients with significant respiratory muscle weakness due to an underlying neuromuscular condition (e.g., myasthenia gravis, amyotrophic lateral sclerosis, or muscular dystrophies) The data and results provided by the BP cuff device are for precheck screening purposes only and cannot be directly used for diagnosis or treatments.

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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iBSM 510(k) summary

eSubmission Number : K243837

Device Name: iBSM

Indications for Use:

iBSM is a wireless monitoring system intended for the display of electrocardiography (ECG) waveform, heart rate measurements, respiratory rate measurement and waveform, functional oxygen saturation of arterial haemoglobin (SpO2), activity, body position, fall detection, skin temperature and Blood Pressure parameter measurements by qualified healthcare professionals in healthcare settings. iBSM continuously monitors the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system provides visual notification when the patient's position has not changed from a preset time threshold.

The iBSM device is intended for use on general care patients who are 18 years of age or older as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment. The iBSM device is not intended for use on critical care patients. The iBSM BP cuff is not intended for subjects that are considered special populations. The iBSM device is indicated for monitoring ECG waveforms and heart rate on non-ambulatory patients.

The iBSM device is intended to be used in wards and patient rooms in professional healthcare facility environment hospital settings. The iBSM device is not intended to be used in Home environment or special environment. The iBSM device is not intended to be used in an ambulatory environment for noninvasive blood pressure, respiratory rate and SpO2 measurement parameters. The iBSM device is not intended to monitor or measure respiratory rate, SpO2, or noninvasive blood pressure while the patient undergoes significant motion or is active. The iBSM device is not intended to be used in the ICU/CCU or Surgery/OT rooms

iBSM is compatible with third-party, FDA cleared devices such as ANNE Chest from Sibel Health Inc, for ECG, HR, RR, body position and skin temperature measurements; and ANNE Limb from Sibel Health Inc. for SpO2 and skin temperature measurements. iBSM is compatible with third-party, FDA-cleared BP devices such as BP2A from Shenzhen Viatom, for noninvasive blood pressure measurements. The iBSM device communicates with an external server for patient data communication and storage.

The iBSM device includes the ability to notify healthcare professionals when physiological data fall outside selected parameters with the use of audio and visual alarms.

The iBSM chest sensor is not intended to be used to provide diagnostic or or interpretive statements to either the patient or the clinician. The iBSM chest sensor is NOT intended to be used on critical care patients and is not a remote diagnostic device. The iBSM chest sensor is NOT intended for use on patients with implanted pacemakers. The iBSM Chest sensor is NOT intended for use on patients with known allergies, or hypersensitivities to, adhesives or nickel. The iBSM Chest Sensor is NOT intended for patients with significant cardiorespiratory disease including patients that are oxygen dependent. The iBSM Chest Sensor is NOT intended for patients with significant respiratory muscle weakness due to an underlying neuromuscular condition (e.g., myasthenia gravis, amyotrophic lateral sclerosis, or muscular dystrophies) The data and results provided by the BP cuff device are for precheck screening purposes only and cannot be directly used for diagnosis or treatments.

Type of Use:

Prescription Only (Part 21 CFR 801 Subpart D)

Submitter:

iOrbit Digital Technologies Private Limited
4th floor, Nagamma Devi Complex, Site No. 22, Survey No. 81/2E, Bannerghatta Main Road
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iBSM 510(k) summary

India

Date Prepared: 25 Feb 2025

Device Information:

Name of the Device : iBSM

510(k) number : K243837

Classification name:Radiofrequency Physiological Signal Transmitter and Receiver

Regulation: 21 CFR §870.2910

Regulatory Class: Class II

Product Classification code: DRG, MWI,FLL,DQA,MWJ,KMI,DXN,BZQ

Predicate Device:

Primary Predicate Device

Trade Name: ANNE One

510(k): K223711

Device Manufacturer: Sibel Health Inc.

Secondary Predicate Device:

Trade Name: ANNE View , Central Hub

510(k): K242842

Device Manufacturer: Sibel Health Inc.

Reference Device:

Trade Name: Blood Pressure Monitor

510(k): K193348

Device Manufacturer: Shenzhen Viatom Technology Co. Ltd.

Reference Device:

Trade Name: ANNE Chest

510(k): K240251

Device Manufacturer: Sibel Health Inc.

Device Description:

The iBSM device is a wireless vital sign and physiological data monitoring device that streams real-time biosignals including electrocardiography (ECG), photoplethysmography (PPG), 3-axis accelerometry, and temperature to measure vital signs such as heart rate(HR), respiratory rate(RR), body position, SpO2 and skin temperature.The waveforms of ECG, Respiration and PPG are also displayed.

The ECG signal is not intended for automated arrhythmia detection or classification. Rather it is intended for manual interpretation, and the automated computation of heart rate through QRS identification using the well-known Pan-Tomkins beat detection algorithm.

The displayed waveform is only intended for display as a check for normal ECG rhythm. The waveform is not intended for manual discrimination of any arrhythmias or cardiac conditions.

The system features two third party FDA cleared skin-mounted, bio-integrated sensors that pair with the iBSM View application for the continuous display and storage of vital sign measurements and physiological waveforms.

The two sensors viz. iBSM chest (Anne Chest from Sibel Health Inc) and iBSM limb (Anne Limb from Sibel Health Inc) sensors are used along with their respective biocompatible adhesives viz. iBSM chest sensor adhesive and iBSM limb sensor adhesives and attached to the patient. The adhesives are intended for a single use, whereas the sensors are intended for multiple reuse with the predefined processing.

Both the chest and the limb sensors along with their adhesives are third party FDA cleared devices.

The system is also compatible with a third-party FDA cleared non-invasive blood pressure measurement device(Blood Pressure monitor BP2A from Shenzhen Viatom Technologies).

iBSM 510(k) summary

The iBSM device consists of a mains powered Docking station that provides the mechanical base station for the iBSM Tablet and has a provision to charge the tablet when docked.

The USB connector provided on the Docking station is intended only to power up the sensor charger accessory and any data transfer to the USB device is disabled.

The iBSM View Application runs on the iBSM tablet in a secure Kiosk mode and is intended to display the patient's physiological parameters and waveforms. The iBSM tablet with the iBSM View application together is termed as iBSM hub,

The physiological data obtained by the sensors are wirelessly transmitted to their respective SDK's that are part of the iBSM hub with Bluetooth (BLE) connectivity, for continuous display of waveforms and parameters on the iBSM View Application. When connected to WiFi, vital signs data can be transferred in real-time from the iBSM hub to an external Server for data storage. The iBSM system provides an FHIR-compatible interface for patient data communication and storage to an external Server.

iBSM is intended to be used only in an hospital environment within the wards or patient rooms and not in ICU/CCU nor in Surgery/OT rooms. It is intended to be used for monitoring of non critical patients. iBSM is not intended to be used in a home environment.

iBSM uses the third party FDA cleared sensors such as ANNE Chest and ANNE Limb from Sibel Health Inc. and BP2A BP Cuff from Shenzhen Viatom, that fulfill the requirements of performance parameters in the signal acquisition before transmitting the data to their SDK's integrated with the iBSM Application in the iBSM hub for displaying the waveforms and the parameters.

The performance attributes of the iBSM system that are responsible for the clinical performance of the device at the point of use are as follows:

1. Heart rate: The device shall calculate HR in the range of 30-270 bpm. The device shall calculate HR with an accuracy of ± 5 bpm or $\pm 10\%$, whichever is greater. HR value calculated by the device shall have a resolution of 1 bpm.
2. Respiratory rate: The device shall calculate RR in the range of 8-35 brpm. The device shall calculate RR with an accuracy within ± 3 brpm. The RR value calculated by the device shall have a resolution of 1 brpm.
3. SpO2: The device shall have an SpO2 detection range to include 70-100%. The device shall have a SpO2 resolution of 1%. The device shall have an SpO2 accuracy (in the range at least 70-100%) within $\pm 3\%$ ARMS for transmissive mode.
4. Temperature: The device shall measure skin temperature with an accuracy of $\pm 0.54^\circ\text{F}$ over the range of $73.2\text{-}109.4^\circ\text{F}$ [$23^\circ\text{C} - 43^\circ\text{C}$ ($\pm 0.3^\circ\text{C}$)]
5. NIBP with a range of 0 - 300 mm Hg and accuracy within ± 3 mm Hg

Indications for Use:

iBSM is a wireless monitoring system intended for the display of electrocardiography (ECG) waveform, heart rate measurements, respiratory rate measurement and waveform, functional oxygen saturation of arterial haemoglobin (SpO2), activity, body position, fall detection, skin temperature and Blood Pressure parameter measurements by qualified healthcare professionals in healthcare settings. iBSM continuously monitors the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system provides visual notification when the patient's position has not changed from a preset time threshold.

The iBSM device is intended for use on general care patients who are 18 years of age or older as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment.

The iBSM device is not intended for use on critical care patients.

The iBSM BP cuff is not intended for subjects that are considered special populations.

The iBSM device is indicated for monitoring ECG waveforms and heart rate on non-ambulatory patients.

The iBSM device is intended to be used in wards and patient rooms in professional healthcare facility environment hospital settings.

The iBSM device is not intended to be used in Home environment or special environment.

The iBSM device is not intended to be used in an ambulatory environment for noninvasive blood pressure, respiratory rate and SpO2 measurement parameters.

The iBSM device is not intended to monitor or measure respiratory rate, SpO2, or noninvasive blood pressure while the patient undergoes significant motion or is active.

The iBSM device is not intended to be used in the ICU/CCU or Surgery/OT rooms

iBSM is compatible with third-party, FDA cleared devices such as ANNE Chest from Sibel Health Inc, for ECG, HR, RR, body position and skin temperature measurements; and ANNE Limb from Sibel Health Inc. for SpO2 and skin temperature measurements.

iBSM is compatible with third-party, FDA-cleared BP devices such as BP2A from Shenzhen Viatom, for noninvasive blood pressure measurements.

The iBSM device communicates with an external server for patient data communication and storage.

iBSM 510(k) summary

The iBSM device includes the ability to notify healthcare professionals when physiological data fall outside selected parameters with the use of audio and visual alarms.

The iBSM chest sensor is not intended to be used to provide diagnostic or interpretive statements to either the patient or the clinician. The iBSM chest sensor is NOT intended to be used on critical care patients and is not a remote diagnostic device. The iBSM chest sensor is NOT intended for use on patients with implanted pacemakers. The iBSM Chest sensor is NOT intended for use on patients with known allergies, or hypersensitivities to, adhesives or nickel. The iBSM Chest Sensor is NOT intended for patients with significant cardiorespiratory disease including patients that are oxygen dependent. The iBSM Chest Sensor is NOT intended for patients with significant respiratory muscle weakness due to an underlying neuromuscular condition (e.g., myasthenia gravis, amyotrophic lateral sclerosis, or muscular dystrophies) The data and results provided by the BP cuff device are for precheck screening purposes only and cannot be directly used for diagnosis or treatments.

Performance Data:

The following consensus standards and bench testing were used and/or referenced to evaluate the substantial equivalence of iBSM with the predicate device.

1. IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements
3. IEC 60601-1-6:2010+AMD1:2013+AMD2:2020: Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
4. IEC 60601-1-8:2006/AMD2:2020: Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
5. Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
6. Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
7. IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
8. IEC 60601-2-47:2012 Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
9. IEC 80601-2-49 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment.
10. ISO 80601-2-56:2017 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
11. ISO 80601-2-61:2017 Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
12. Cybersecurity evaluation according to the requirements of the FDA draft guidance document, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.
13. Usability testing in accordance with the FDA guidance document, Applying Human Factors and Usability Engineering to Medical Devices and IEC 62366-1:2020. iBSM Human factor tests as per FDA guidance
14. iBSM Software verification testing according to IEC 62304:2015 and the FDA guidance document, Content of Premarket Submissions for Software Contained in Medical Devices.
15. iBSM Wireless coexistence testing per ANSI C63.27
16. iBSM System Functional and performance verification tests
17. iBSM Mechanical tests
18. iBSM Electrical tests
19. Verification of the iBSM alarm system to IEC 60601-1-8:2020
20. iBSM Packaging validation test as per ASTM D4169
21. Assessment of Software of Unknown Provenance per the FDA guidance document, Off-The-Shelf Software Use in Medical Devices.

The iBSM third party FDA cleared Chest sensor (ANNE Chest sensor from Sibel Health Inc) conforms to the following guidance and standards: per K240251.

- Electrical safety and electromagnetic compatibility testing according to ANSI/AAMI ES60601-1:2005/(R) 2020 and IEC 60601-1-2:2014 standards. Electrical safety testing in the home healthcare environment per IEC 60601-1-11:2015.
- Biocompatibility testing according to ISO 10993-5:2009, ISO 10993-10:2021, and ISO 10993-23:2021 for patient contacting materials.

iBSM 510(k) summary

- Wireless coexistence testing according to ANSI IEEE C63.27-2017.
- Software verification and validation testing according to IEC 62304:2015 and the FDA guidance document, Content of Premarket Submissions for Software Contained in Medical Devices.
- Safety and performance testing of ECG per IEC 60601-2-27:2011 and IEC 60601-2-47:2012.
- Defibrillation testing according to Section 8.5.5 of ANSI/AAMI ES60601-1:2005/(R)2012
- Shelf life testing of the adhesive to demonstrate performance over the intended device life cycle.
- Bench testing to demonstrate the mechanical durability of the sensors.
- Usability testing in accordance with the FDA guidance document, Applying Human Factors and Usability Engineering to Medical Devices.
- Performance testing of heart rate, respiratory rate, skin temperature, activity, and posture.
- Cybersecurity evaluation according to the FDA guidance document, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

The iBSM third party FDA cleared Limb sensor (ANNE Limb sensor from Sibel Health Inc) conforms to the following guidance and standards , per K240305

- Electrical safety and electromagnetic compatibility testing according to ANSI/AAMI ES60601-1:2005/(R)2012 and IEC 60601-1-2 Edition 4.0 2014 standards. Electrical safety testing in the home healthcare environment per IEC 60601-1-11:2015.
- Biocompatibility testing according to ISO 10993-5:2009 and ISO 10993-10:2010 for patient contacting materials.
- Wireless coexistence testing according to ANSI IEEE C63.27-2017.
- Software verification and validation testing according to IEC 62304:2015 and the FDA guidance document, Content of Premarket Submissions for Software Contained in Medical Devices.
- Safety and performance testing of ECG per IEC 60601-2-27:2011 and IEC 60601-2-47:2012.
- Shelf life testing of the adhesive to demonstrate safety and performance over the intended device life cycle.
- Bench testing to demonstrate the mechanical durability of the sensors.
- Usability testing in accordance with the FDA guidance document, Applying Human Factors and Usability Engineering to Medical Devices.
- Performance testing of pulse rate and skin temperature.
- Cybersecurity evaluation according to the FDA guidance document, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

The iBSM third party FDA cleared BP Cuff device (Blood pressure BP2A from Shenzhen Viatom) conforms to the following guidances and standards , per K193348

- Non-Invasive Blood Pressure (NIBP) Monitor Guidance ANSI AAMI ES60601-1:2005+A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance; IEC 60601-1-2:2014
- Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.
- ISO 10993-5: 2009 /(R)2014 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity; ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
- IEC 80601-2-30: 2018 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 80601-2-47: 2012 Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems 47 CFR FCC PART 15. Subpart C Unintentional Radiators/ Miscellaneous Wireless Communications Service

Conclusion:

The results of the substantial equivalence assessment of indications for use, intended use, patient population, use environment, device performance parameter features, technological characteristics with physiological data acquisition with same type of sensors and data communication, taken together with safety and performance testing data, demonstrate that iBSM's performance characteristics are substantially equivalent to the predicate device in both technology and intended use.

Comparison chart

Device Type and Manufacturer	Subject device iBSM iOrbit Digital Technologies	Primary Predicate Device ANNE One Sibel Health Inc	Secondary Predicate Device ANNE View, Central Hub Sibel Health Inc	Reference Device Blood Pressure Monitor Shenzhen Viatom	Ref Device ANNE Chest Sibel Health Inc	Equivalent/Similar / Variant Equivalent : Same contents as in subject and predicate or reference devices Similar: Similar between the devices with a rationale Different/Variant : Not same between the subject device and the predicate or reference device
Trade Name	iBSM	ANNE One	ANNE View	BP2A	ANNE Chest	
510(k) Number	K243837	K223711	K242842	K193348	K240251	
Class	II	II	II	II	II	Equivalent
Product code	DRG, MWI, FLL, DQA, MWJ, KMI, DXN, BZQ	DRG, MWI, FLL, DQA, MWJ, KMI	MSX, MWI, KMI	DXN, DPS	DRG,FLL,KMI,MWJ, BZQ,MWI	Equivalent as in K223711 for the following codes: DRG is primary code. DRG: Transmitters And Receivers, Physiological Signal, Radiofrequency, ClassII MWI: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms), Class II FLL:Thermometer, Electronic, Clinical DQA:Oximeter MWJ:Electrocardiograph, Ambulatory (Without Analysis) KMI:Monitor, Bed Patient Equivalent to K193348 for the following code. DXN:System, Measurement, Blood-Pressure, Non-Invasive Equivalent : For BZQ product code the primary predicate device did monitor breathing frequency. and K240251 supported the same. The above two in combination support the subject device for BZQ.
Regulation No.	870.2910'	870.2910'	870.23	21 CFR 870.1130	870.2910 Transmitters and Receivers,Physiological	Equivalent as in K223711 for the primary product code

iBSM 510(k) summary

					Signal,Radiofrequency	
Regulation name	Transmitters and Receivers, Physiological Signal, Radiofrequency	Transmitters and Receivers, Physiological Signal, Radiofrequency	Cardiac monitor (including Cardiotachometer and rate alarm)	Noninvasive Blood Pressure Measurement System		Equivalent as in K223711 for the primary product code

<p>Indications for Use</p>	<p>iBSM is a wireless monitoring system intended for the display of electrocardiography (ECG) waveform, heart rate measurements, respiratory rate measurement and waveform, functional oxygen saturation of arterial haemoglobin (SpO2), activity, body position, fall detection, skin temperature and Blood Pressure parameter measurements by qualified healthcare professionals in healthcare settings. iBSM continuously monitors the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system provides visual notification when the patient's position has not changed from a preset time threshold.</p> <p>The iBSM device is intended for use on general care patients who are 18 years of age or older as a general patient monitor to provide continuous physiological information as an aid to diagnosis and treatment. The iBSM device is not intended for use on critical care patients. The iBSM BP cuff is not intended for subjects that are considered special populations. The iBSM device is indicated for monitoring ECG waveforms and heart rate on non-ambulatory patients.</p> <p>The iBSM device is intended to be used in wards and patient rooms in professional healthcare facility environment hospital settings. The iBSM device is not</p>	<p>ANNE One is a wireless monitoring platform indicated for the measurement of electrocardiography (ECG) waveforms, heart rate, respiratory rate, functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, activity, body position, fall detection, skin temperature, and body temperature by qualified healthcare professionals in home and healthcare settings. ANNE One is compatible with third-party, FDA-cleared devices for noninvasive blood pressure, SpO2, pulse rate, and body temperature measurements. The device is indicated for monitoring ECG waveforms and heart rate on ambulatory patients. The device is not intended to monitor or measure respiratory rate, SpO2, pulse rate, or noninvasive blood pressure while the patient undergoes significant motion or is active. ANNE One continuously monitors the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system provides visual notification when the patient's position has not changed from a preset threshold of time. The device is intended for use on general care patients who are 12 years of age or older as a general patient</p>	<p>The ANNE View application is intended for the display of physiological data from the ANNE Chest and ANNE Limb devices. The application is also compatible with Third-party, FDA-cleared devices for the display of noninvasive blood pressure, SpO2, pulse rate, and body Temperature measurements. The ANNE View application notifies Healthcare professionals when physiological data fall outside selected parameters. The ANNE View application displays the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system notifies the user when the patient's position has not changed for a preset threshold of time. The ANNE View application communicates to compatible central monitoring platforms, including the Central Hub, for the display and storage of multiple patients' physiological data. The Central Hub has the ability to notify healthcare professionals when physiological data</p>	<p>The device is intended to measure blood pressure or electrocardiogram (ECG) in home or healthcare facilities environment. The device is a blood pressure monitor intended for use in measuring blood pressure and pulse rate in the adult population. The device is intended to measure, display, store and review adults' single channel ECG rhythms and gives some suggested symptoms such as regular beat, irregular beat, low HR and high HR. The ECG part of the device is for Rx only, and the blood pressure part is for OTC.</p>	<p>The ANNE Chest is a wearable, wireless sensor intended for the measurement of electrocardiography (ECG) waveforms, heart rate, respiratory rate, activity, fall detection, body position, and skin temperature. The ANNE Chest sensor is not intended to monitor or measure respiratory rate while the patient undergoes significant motion or is active. The ANNE Chest sensor Communicates with compatible software applications for the display, storage, and analysis of Data. The device is intended to provide Continuous physiological information as an aid to Diagnosis and treatment by healthcare Professionals in general care patients who are 12 Years of age or older in clinical and home Environments. The device is not intended for use on Critical care patients</p>	<p>Equivalent to K223711 for the intended use of ECG, HR, RR, SpO2, Activity, Body position, fall detection and skin temperature, Both iBSM and ANNE One intended to be used in a hospital setting. No pulse rate and body temperature measurements in iBSM unlike Anne One, and these additional features does not affect the safety and performance of the iBSM device</p> <p>Equivalent to K193348 for use of BP in a hospital environment. Equivalent to K223711 and K242842 for the patient population above 18 years of age, and non-critical patients</p> <p>Equivalent to K242842 for the data transmission to an external remote server. Equivalent to K242842 for the audio and visual alarms</p>
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	<p>intended to be used in Home environment or special environment. The iBSM device is not intended to be used in an ambulatory environment for noninvasive blood pressure, respiratory rate and SpO2 measurement parameters. The iBSM device is not intended to monitor or measure respiratory rate, SpO2, or noninvasive blood pressure while the patient undergoes significant motion or is active. The iBSM device is not intended to be used in the ICU/CCU or Surgery/OT rooms</p> <p>iBSM is compatible with third-party, FDA cleared devices such as ANNE Chest from Sibel Health Inc, for ECG, HR, RR, body position and skin temperature measurements; and ANNE Limb from Sibel Health Inc. for SpO2 and skin temperature measurements. iBSM is compatible with third-party, FDA-cleared BP devices such as BP2A from Shenzhen Viatom, for noninvasive blood pressure measurements. The iBSM device communicates with an external server for patient data communication and storage.</p> <p>The iBSM device includes the ability to notify healthcare professionals when physiological data fall outside selected parameters with the use of audio and visual alarms.</p> <p>The iBSM chest sensor is not intended to be used to provide diagnostic or or interpretive</p>	<p>monitor to provide continuous physiological information as an aid to diagnosis and treatment. The data from ANNE One are transmitted wirelessly for display, storage, and analysis. The device is not intended for use on critical care patients.</p>	<p>fall outside selected parameters. The ANNE View and Central Hub are intended for use by trained, qualified healthcare professionals in the clinical or home Healthcare environment. The device is not intended for use on critical care patients.</p>			
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	<p>statements to either the patient or the clinician. The iBSM chest sensor is NOT intended to be used on critical care patients and is not a remote diagnostic device. The iBSM chest sensor is NOT intended for use on patients with implanted pacemakers. The iBSM Chest sensor is NOT intended for use on patients with known allergies, or hypersensitivities to, adhesives or nickel. The iBSM Chest Sensor is NOT intended for patients with significant cardiorespiratory disease including patients that are oxygen dependent. The iBSM Chest Sensor is NOT intended for patients with significant respiratory muscle weakness due to an underlying neuromuscular condition (e.g., myasthenia gravis, amyotrophic lateral sclerosis, or muscular dystrophies) The data and results provided by the BP cuff device are for precheck screening purposes only and cannot be directly used for diagnosis or treatments.</p>					
Target Population	18 years or older	12 years of age or older	----- -	Adult	12 years of age and older	Both subject and the predicate devices are used for target populations of above 18 years. Equivalent.
Use Environment	Healthcare setting	Home and Healthcare setting	Home and Healthcare setting	Home use, Healthcare facilities	Home and Healthcare settings	Both subject and the predicate devices are used in hospital healthcare settings. Equivalent.
Sensor Placement	Finger and Chest for the Limb and Chest sensors respectively. BP sensor on upper arm	Finger and Chest	----- -	BP measurement: Upper arm ECG Recording: Right hand to left hand (Lead I), right hand to left abdomen (Lead II)	Chest	Equivalent as in K223711 for the chest and limb sensors. Equivalent to K223711 that uses optional third party NIBP sensor Equivalent as in K193348 for the BP cuff sensor for NIBP parameters measurement only.

						ECC recording from NIBP cuff is not intended for iBSM and it does not affect the safety and performance of iBSM
Heart Rate	30-270 bpm (the greater of $\pm 10\%$ or ± 5 bpm)	30-300 bpm (the greater of $\pm 10\%$ or ± 5 bpm)			30-270bpm (the greater of $\pm 10\%$ or ± 5 bpm)	Similar as the HR specs of subject iBSM device are contained within the wider range of specs of the predicate device as in K223711
Respiratory rate	Accelerometer-derived 8 - 30 bpm (± 3 bpm MAE)	Accelerometer-derived 8 - 30 bpm (± 3 bpm MAE)			Accelerometer and ECG derived 8-35bpm (± 3 bpmRMSE)	Equivalent as in K223711
Skin Temperature	73.4°F - 109.4°F ($\pm 0.54^\circ\text{F}$) 23°C - 43°C ($\pm 0.3^\circ\text{C}$)	73.4°F - 109.4°F ($\pm 0.54^\circ\text{F}$) 23°C - 43°C ($\pm 0.3^\circ\text{C}$)			73.4°F-109.4°F($\pm 0.54^\circ\text{F}$) 23°C-43°C($\pm 0.3^\circ\text{C}$)	Equivalent as in K223711
SpO2	ARMS $\leq 3\%$ (range 70-100%)	ARMS $\leq 3\%$ (range 70-100%)			Not Applicable	Equivalent as in K223711
Activity Posture	Accelerometer Body Position Fall detection	Accelerometer Body Position Fall detection			Accelerometer , Body position	Equivalent as in K223711
Non-Invasive Blood Pressure (NIBP)	0 - 300 mmHg (± 3 mmHg)	0 - 300 mmHg (± 3 mmHg)		Pressure: 0 to 300mm Hg		Equivalent as in K223711 and K193348
ECC Waveform display	Compliant to IEC 60601-2-27 Compliant to IEC 60601-2-47	Compliant to IEC 60601-2-27 Compliant to IEC 60601-2-47			Compliant to IEC 60601-2-27 Compliant to IEC 60601-2-47	Equivalent as in K223711
ECC Sampling Frequency	ECC Sampling Frequency: 512 Hz Streaming Frequency: 256 Hz	ECC Sampling Frequency: 512 Hz Streaming Frequency: 256 Hz			ECC Sampling Frequency: 512Hz Streaming Frequency:256 Hz	Equivalent as in K223711
ECC Resolution	18 bit	18 bit			18 bit	Equivalent as in K223711
Data	Data is transmitted wirelessly via Bluetooth from the sensors to a mobile device.Data may be downloaded for later storage and analysis.	Data is transmitted wirelessly via Bluetooth from the sensors to a mobile device.Data may be downloaded for later storage and analysis.			Data is transmitted Wirelessly via Bluetooth From the sensor to the SibelSDK, which may be integrated within software applications for the display and storage of data.	Equivalent as in K223711
Notification	Provides visual notification on patient orientation.	Provides visual notification on patient orientation.			No notification ability	Equivalent as in K223711

Motion	Respiratory rate, SpO2, measurements should not be taken during motion. Heart rate and ECG may be taken during motion.	Respiratory rate, SpO2, and pulse rate measurements should not be taken during motion. Heart rate and ECG may be taken during motion.			Respiratory rate measurements should not be taken during motion. Heart rate and ECG may be taken during motion.	Equivalent as K223711
Measurement modality	Continuous Measurements: Respiratory rate, ECG, heart rate, SpO2, skin temperature, body position and Blood pressure.	Continuous Measurements: Respiratory rate, ECG, heart rate, SpO2, pulse rate, skin temperature, body position Spot Check Measurements with third party devices: Blood pressure, body temperature			Continuous measurement	Similar as in K223711. The HR, RR, ECG, SpO2, skin temperature, body position, Blood pressure monitoring is equivalent in the subject device iBSM and the primary predicate device Anne One.
Monitoring Type	Real time monitoring Data storage for later analysis	Real time monitoring Data storage for later analysis			Real time monitoring	Equivalent as in K223711
Alarms	Visual and auditory alarms	No alarming capabilities Visual alerts for turn management.	Visual and auditory alarms		Not an apnea alarm	Similar as in K242842 Note: iBSM conform to Alarm standards IEC 60601-1-8
BP Working principle	Blood Pressure measurement: Oscillometric method			Blood Pressure measurement: Oscillometric method		Equivalent as in K172329 Equivalent in K233711 Anne One as it utilizes the third party BP sensor from Shenzhen Viatom
Pressure sensor	Semiconductor pressure sensor			Semiconductor pressure sensor		Equivalent as in K172329
Internal power supply for BP Cuff sensor	Rechargeable lithium polymer battery for the BP cuff meter			Rechargeable lithium polymer battery		Equivalent as in K172329
Cuff size	22-42 cm			22-42 cm		Equivalent as in K172329
Measuring range NIBP	Pressure: 0 to 300mm Hg			Pressure: 0 to 300mm Hg		Equivalent as in K172329
Accuracy (NIBP)	Pressure: ±3mmHg			Pressure: ±3mmHg		Equivalent as in K172329
BP Materials	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance			Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance		Equivalent as in K172329

Display for BP cuff meter	BP measurement from the sensor to the iBSM Hub App.			BP measurement: LCD (Liquid Crystal Display) displays; systolic blood pressure diastolic blood pressure pulse rate ECG recording:ECG rhythmHeart Rate Regular beat, Irregular beat, High HR Low HR		Similar as in K172329. ECG measurement using BP cuff display is not applicable for iBSM
Input Impedance for BP cuff meter	≥10MΩ, 10Hz			≥10MΩ, 10Hz		Equivalent as in K172329
CMRR for BP cuff meter	>60 dB			>60 dB		Equivalent as in K172329
Bluetooth transmission	The device has wireless Bluetooth LE transmission.			The device has wireless Bluetooth LE transmission.		Equivalent as in K172329
Operating System	Android 12		ANNE View - Android 14.0			Similar, Common Android OS. Version difference does not impact patient safety or performance as the full application is tested and verified for the specific configuration
Communication Method	iBSM data communication within the device from sensors to the hub using Bluetooth BLE. iBSM communicates data to an external server over WiFi LAN		The ANNE View application communicates with compatible medical devices over Bluetooth. The Central Hub receives data from ANNE View over LAN or WLAN.			iBSM is not intended to communicate with other compatible medical devices over Bluetooth. iBSM communicates the patient data to an external server for storage.
Monitoring type	iBSM provides the real time monitoring. iBSM communicates with an external server for patient data and storage.		The ANNE View application provides real time monitoring. The Central Hub provides real time monitoring and data storage for later analysis.			Equivalent for real time monitoring of patient physiological parameters on the device. iBSM does not provide a CMS application for remote real time view.
Interoperability	The iBSM system consists of iBSM Chest sensor , ANNE limb sensor and BP Cuff sensor as part of its inherent product configuration , with internal Bluetooth communication.		The ANNE View application is interoperable with the ANNE Chest Sensor and the ANNE Limb Sensor. The ANNE View application is also interoperable with third party compatible			iBSM devices with the sensors and application is not intended to be interoperable to other third party sensors or applications. This does not impact the safety and performance of the iBSM device. Only matched sensors as specified in the iBSM labeling are applicable to iBSM.

			<p>devices for non-invasive blood pressure, SpO2, pulse rate, and body Temperature monitoring. The ANNE View application is interoperable with central monitoring platforms including the Central Hub.</p>			
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