July 6, 2023

SCHILLER AG
Stefan Bigler
Head of Regulatory Affairs
Altgasse 68
CH-6341 Baar
Switzerland

Re: K221056
Trade/Device Name: ARGUS PB-3000
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: July 6, 2023
Received: July 6, 2023

Dear Stefan Bigler:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Shruti N. Mistry -S

Jennifer Shih Kozen
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)*
K221056

Device Name
ARGUS PB-3000

Indications for Use *(Describe)*

The ARGUS PB-3000 is a vital data acquisition unit intended to be used within or connected to a medical device or a medical system (Host System) for acquiring, analysing, and transmission of patient vitals and other pertinent clinical data of following vital data of a patient.

Indicated for the following applications:

ECG monitoring and diagnostic - The ECG monitoring function provide a conventional information about the patient's ECG rhythm, heart rate, and may be used for the diagnostic measurements, interpretation and arrhythmias detection in a medical device or medical system (Host System).
Respiration rate and apnea monitoring is indicated for pneumatic issues.

IBP - Invasive blood pressure monitoring is indicated for use in patients who require continuous monitoring of physiological pressures in order to rapidly assess changes in the patient's condition or response to therapy. It may also be used to aid in medical diagnosis.

NIBP - NIBP measurement is indicated in patients who have a risk of developing high or low blood pressure.

SpO2 - These measurements are indicated for use in patients who are at risk of developing hypoxemia, carboxyhemoglobinemia, or methemoglobinemia. This monitoring may be used during no motion and motion conditions, and in patients who are well or poorly perfused.

CO2 - The CO2 measurement is used to detect trends in the level of inspired or expired CO2. It is used for monitoring breathing efficacy and treatment effectiveness in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully.
Respiration rate and apnea monitoring is indicated for pneumatic issues.

Cardiac Output (CO) - Cardiac Output measurement is indicated for use in patients who require a non-continuous measurement of the stroke volume and l/min volume of the heart.

Temperature - Temperature measurement is indicated in any patient that has a risk of high or low temperature.

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.

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# 510(k) Summary

## 1. Submitter's Name, Address, Contact Information


| | |
|---|---|
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Date prepared: July 5, 2023

## 2. Subject Device and Predicate Device

### 2.1. Subject Device

| | |
|---|---|
| Device Trade Name | ARGUS PB-3000 |
| Common / Usual Name | Monitoring system |
| Classification Name | Monitor, Physiological, Patient<br>(With Arrhythmia Detection or Alarms) |
| Device Class | II |
| Product code | MHX |
| Regulation Number | 21 CFR 870.1025 |

### 2.1. Predicate Device

| | |
|---|---|
| Device Name | ARGUS PB-1000 System |
| 510(k) number | K012226 |
| Device Class | II |
| Product code | MHX |
| Regulation Number | 21 CFR 870.1025 |

## 3. Device Description

The ARGUS PB-3000 is a vital data acquisition unit intended to be used within or connected to a medical device or a medical system (Host System) for acquiring, analysing, and transmission of patient vitals and other pertinent clinical data. It receives vital signals from the patient through external sensors and communicates with the Host System. Data is transmitted to the Host System via network connection and without storing vital data and patient demographic data on the PB-3000. Depending on the variant of the PB-3000, the device has different modules allowing measurement of the vital parameter for ECG (monitoring and diagnostic mode, and respiration), IBP, temperature, cardiac output (CO), SpO2, CO2, and/or NIBP measurements.

The Host System is designed by a 3rd party host system manufacturer who chooses the PB-3000 variant to be implemented in their Host System. The PB-3000 communication interface allows the Host System Manufacturer to setup and use the provided functions.

## 4. Intended Use and Indications for Use

### 4.1. Intended Use

The **ARGUS PB-3000** is a vital data acquisition unit intended to be used within or connected to a medical device or a medical System (Host System) for acquiring, analysing, and transmission of patient vitals and other pertinent clinical data of following vital data of a patient:

**ECG and Respiration**
ECG, heart rate, asystole time, respiration rate and apnoea time for monitoring and diagnostic purpose.

**IBP**
The IBP measurement is intended for continuously invasive measurement of a patient's arterial and/or venous blood pressure in different locations.

**NIBP**
The NIBP measurement is intended for non-invasive measure blood pressure with different cuffs in different locations.

**$SpO_2$**
The SpO2 measurement is intended for non-invasive measuring of a patient's oxygen saturation level and other parameters (e.g. SpCO, SpMet).

**$CO_2$ and Respiration**

The CO2 measurement is intended for the non-invasive monitoring of a patient's in and exhaled carbon dioxide, anaesthesia gases and to provide a respiration rate.

**Cardiac Output (CO)**
The Cardiac Output measurement is intended for measuring continuously blood and injected fluid temperature for calculating the current Cardiac Output of a patient in the medical system (Host System).

**Temperature**
The Temperature measurement is intended for non-invasive and invasive measurement of a patient's temperature in different locations.

## 4.2. Indications for Use

The **ARGUS PB-3000** is a vital data acquisition unit intended to be used within or connected to a medical device or a medical system (Host System) for acquiring, analysing, and transmission of patient vitals and other pertinent clinical data of following vital data of a patient.

Indicated for the following applications:

**ECG monitoring and diagnostic**
The ECG monitoring function provide a conventional information about the patient's ECG rhythm, heart rate, and may be used for the diagnostic measurements, interpretation and arrhythmias detection in a medical device or medical system (Host System).
Respiration rate and apnea monitoring is indicated for pneumatic issues.

**IBP**
Invasive blood pressure monitoring is indicated for use in patients who require continuous monitoring of physiological pressures in order to rapidly assess changes in the patient's condition or response to therapy. It may also be used to aid in medical diagnosis.

**NIBP**
NIBP measurement is indicated in patients who have a risk of developing high or low blood pressure.

**$SpO_2$**
These measurements are indicated for use in patients who are at risk of developing hypoxemia, carboxyhemoglobinemia, or methemoglo-binemia. This monitoring

may be used during no motion and motion conditions, and in patients who are well or poorly perfused.

**$CO_2$**

The CO2 measurement is used to detect trends in the level of inspired or expired CO2. It is used for monitoring breathing efficacy and treatment effectiveness in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully.
Respiration rate and apnea monitoring is indicated for pneumatic issues.

**Cardiac Output (CO)**

Cardiac Output measurement is indicated for use in patients who require a non-continuous measurement of the stroke volume and l/min volume of the heart.

**Temperature**

Temperature measurement is indicated in any patient that has a risk of high or low temperature.

## 5. Comparison of Indications

Both the predicate device and the subject device are patient monitoring systems intended to be used in healthcare facilities under the direction of clinical professionals.

The PB-3000 is a vital signs data acquisition unit, lacking a display, and intended to be used within or connected to a medical device or a medical system (Host System); the PB-1000 was cleared with its own monitoring system as a complete patient monitoring system, and the parameter unit of PB-1000 could also be integrated in compatible Host Systems.
When the PB-3000 is integrated into compatible host systems, the host provides the visual display, can perform analysis on the PB-3000 acquired data, and perform alarm handling.

The predicate and subject are substantially equivalent because the PB-3000 must integrate with a Host System that then will manage the alarm system, and uses PB-3000 data further analyses (e.g., arrythmia or ST segments, trending) – which is equivalent to the function of the PB-1000 with both a parameter box and a visualization unit which is a system that includes both a parameter box and a visualization unit.

## 6. Comparison of Technological Characteristics with the Predicate Device

| Description | Subject Device<br>ARGUS PB-3000 | Predicate Device<br>K012226 - ARGUS PB-1000 | Comparison |
|---|---|---|---|
| Target population | The Argus PB-3000 is used in medical device or medical system (Host System) and intended to be used for the patient target group:<br>• Adult and pediatric (neonates to adolescent)<br>• Both sexes and all races | Measuring ranges, alarm limits and sensors can be selected for the individual requirements of the patient (neonates, children, adults).<br>NIBP Sensors: Different cuff sizes for adults, children and neonates<br><br>Pulsoximetry SpO2Finger clip sensor, adhesive sensors for adults, children and neonates<br><br>etCO2Sensors: Mainstream: Airway adapter for adults and neonates (low dead space) | The PB-3000 and the PB-1000 have the same target population. |
| Where used | The **ARGUS PB-3000** may be used in the operating suite, intensive care unit, emergency medical services environment and road ambulances. It is fixed to a wall, the patient bed, a trolley, or is incorporated into a medical device or medical system (Host System) upwards or at a 90° position. | The system is intended for use in the Intensive Care Unit, in the Recovery Room, in the Operation Room and during hospital internal transport. | The PB-3000 is substantially equivalent to the PB-1000: The PB-3000 additionally can be used in road ambulances. Differences do not raise new questions on safety and effectiveness. |
| Display Information | No display provided. Must integrate into compatible Host System (subject to further V&V and regulatory authorization) | PB-1000 Display Unit | Substantially Equivalent. Testing demonstrates that the PB-3000 performs appropriate vital signs data acquisition and transfers these data to a compatible host system for a display equivalent to predicate. |
| Power | Main input: Power supply with 100-240 VAC<br>Output: 15V<br>or guaranteed medical power supply 15 VDC ±5% supplied by OEM host system<br>Back-up Internal rechargeable battery | Main input: Argus PRO (100 -240 VAC)<br>Output: 7 to 12 VDC<br>Power consumption: <15 W<br><br>Internal rechargeable battery | Substantially Equivalent: Difference does not raise new questions of safety or effectiveness as demonstrated by 60601-1 testing |
| Electrical Safety | IEC 60601-1:2005 + C1:2006 + C2:2007 + A1:2012 and US deviations | 60601-1 | Substantially Equivalent |

| Description | Subject Device<br>ARGUS PB-3000 | Predicate Device<br>K012226 - ARGUS PB-1000 | Comparison |
|---|---|---|---|
| EMC | IEC 60601-1-2:2020 (ed 4.1) | 60601-1-2 | Substantially Equivalent |
| ECG | • Simultaneous recording of all active electrode signals<br>• Use with 5 and 10 wire patient cable<br><br>**Parameters**<br>Heart rate and Asystole | • Simultaneous recording of all active electrode signals<br>• Use with 3, 5 and 10 wire patient cable<br><br>**Parameters**<br>Heart rate and Asystole<br>ST segment analysis<br>Resting ECG and arrythmia | Substantially Equivalent<br>PB-3000 complies with 60601-2-25 for diagnostic ECGs andcompatible host system shall be responsible for ST analysis, resting ECG, and arrythmia analysis, if indicated. |
| Respiration | Thorax impedance method<br>**Parameter** Respiration rate, apnoea | Thorax impedance method<br>**Parameter** Respiration rate, apnoea | Substantially Equivalent |
| IBP Parameters | SYS, MEAN, DIA | SYS, MEAN, DIA | Substantially Equivalent |
| NIBP Parameters | systolic, diastolic and mean pressure with different cuff sizes for adults, children, and neonates | systolic, diastolic and mean pressure with different cuff sizes for adults, children, and neonates | Substantially Equivalent |
| SpO2 | Masimo™ MX5 (K193242)<br>Sensors: Finger clip sensor, adhesive sensors for adults, children and neonates | MASIMO™ SET MS-1 (K962603)<br>Sensors: Finger clip sensor, adhesive sensors for adults, children and neonates | Substantially Equivalent |
| CO2 | Fully isolated, defibrillation protected >5 kV | Fully isolated, defibrillation protected >5 kV | Substantially Equivalent |
| Cardiac Output | Thermodilution<br>Injectate temperature waveform and catheter temperature | Thermodilution<br>Injectate temperature waveform and catheter temperature | Substantially Equivalent |
| Temperature | Direct temperature operating mode Sensors for rectal use, skin, ear, esophageal | Direct temperature operating mode; and includes temperature differential<br><br>Sensors for rectal use, skin, ear | Substantially Equivalent. PB-3000 is part of a compatible host system that can provide temperature differential. |
| Alarms | Acquires data that are transferred to Host, provides technical states, and audio communication | Visual and audible alarms | Substantially Equivalent. In PB-3000, alarm handling is implemented on the host system using data and event states acquired by the PB-3000. |

The ARGUS PB-3000 and ARGUS PB-1000 Unit (Parameter Box) are part of a medical devices system: Both units have modules for acquiring, analyzing, and transmission of patient vital data and the ability to communicate with the medical device system (Host System). They receive vital signs from the patient through external sensors for ECG/respiration, IBP, body temperature, cardiac output (CO), SpO2, CO2, and/or NIBP measurement.

## 7. Non-Clinical Performance Data

### 7.1. Electrical Safety

| Rec.# | Standard Year (ed.) | Title |
|---|---|---|
| N/A | IEC 60601-1:2005, AMD1:2012 (ed. 3.1) | Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance |
| 19-4 | ANSI AAMI ES60601-1:2005/ (R)2012 | Medical electrical equipment—Part 1: General requirements for basic safety and essential performance |

### 7.2. EMC

| Rec.# | Standard Year (ed.) | Title |
|---|---|---|
| 19-36 | 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 |

### 7.3. Additional Standards Testing and V&V

| Rec.# | Standard Year (ed.) | Title |
|---|---|---|
| 5-89 | IEC 60601-1-6:2010 + A1 2013 (ed. 3.1) | Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability |
| 19-15 | IEC 60601-1-12:2014 (ed. 1.0) | Medical electrical equipment-Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment |
| 3-105 | IEC 60601-2-25:2011 (ed. 2.0) | MEDICAL ELECTRICAL EQUIPMENT – Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of electrocardiographs |

| Rec.# | Standard Year (ed.) | Title |
|---|---|---|
| 3-126 | IEC 60601-2-27:2011 (ed. 3.0) | Medical electrical equipment Part 2: Particular Requirements for the Safety, Including Essential Performance of Electrocardiographic Monitoring Equipment |
| 3-123 | IEC 80601-2-30:2018 (ed. 2.0) | Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers |
| 3-115 | IEC 60601-2-34:2011 (ed. 3.0) | Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment |
| N/A | IEC 80601-2-49:2018 (ed. 1) | Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors |
| 1-140 | ISO 80601-2-55:2018 (ed. 2.0) | Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors |
| 6-421 | ISO 80601-2-56:2017, AMD1: 2018 (ed. 2.0) | Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement |
| 1-139 | ISO 80601-2-61:2017 (ed. 2), COR1:2018 | Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment |
| 5-114 | IEC 62366-1 :2015 (ed. 1) / COR1: 2016 | Medical devices – Application of usability engineering to medical devices |
| 3-118 | ANSI/AAMI EC57:2012 | Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms |
| 5-125 | ISO 14971:2019 (ed. 3) | Medical devices - Application of risk management to medical devices |
| 3-166 | EN ISO 81060-2:2018 (ed. 3) | Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type |

- Testing of the ECG module using standard ANSI/AAMI EC57:2012 (FDA recognition # 3-118) to verify the sensitivity and positive predictivity of the QRS detection and heart rate calculation
- Performance testing of ECG-based respiration measurement accuracy in the ARGUS PB-3000 to support performance equivalence compared to the predicate device.
- Performance testing for the cardiac output measurement function (accuracy)
- Compatibility testing and verification for all compatible temperature sensors, IBP accessories, and NIBP cuffs
- Standards-based testing and system level testing for the $SpO_2$ and $CO_2$ modules to verify module functionality as implemented in PB-3000

### 7.4. Software Verification and Validation Testing

| Rec.# | Standard Year (ed.) | Title |
|---|---|---|
| 13-79 | IEC 62304:2006 + A1:2015 (ed. 1.1) | Medical device software Software life-cycle processes |

Software Verification and Validation testing was performed at the unit, integration and system levels for the ARGUS PB-3000 software to ensure it meets all specifications. In all instances, ARGUS PB-3000 functioned as intended and the observed results demonstrate substantial equivalence with the predicate device.

## 8. Clinical Testing

No clinical testing was performed for ARGUS PB-3000.

## 9. Conclusion

The ARGUS PB-3000, the subject device of this submission, is substantially equivalent to its predicate device, the ARGUS PB-1000 System (K012226). ARGUS PB-3000 has the same intended use and substantially equivalent indications for use, design, and functions as the predicate device. Non-clinical performance testing demonstrates that PB-3000 meets its requirements and is as safe and effective as its predicate device. The technological differences between ARGUS PB-3000 and its predicate device raise no new questions of safety or effectiveness. Thus, ARGUS PB-3000 is substantially equivalent to the previously cleared predicate device.