May 25, 2023

Saranas Inc.
% Allison Komiyama
Consultant
RQM+
2251 San Diego Ave.
Suite B-257
San Diego, California 92110

Re: K230273
Trade/Device Name: Saranas Early Bird Bleed Monitoring System
Regulation Number: 21 CFR 870.1345
Regulation Name: Intravascular bleed monitor
Regulatory Class: Class II
Product Code: QFJ
Dated: January 31, 2023
Received: January 31, 2023

Dear Allison Komiyama:

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,

Robert T. Kazmierski -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.

Submission Number *(if known)*

Device Name

Saranas Early Bird Bleed Monitoring System

Indications for Use *(Describe)*

The Early Bird is indicated for the introduction of catheters, catheter balloons, and other diagnostic and interventional devices into the femoral artery or femoral vein while maintaining hemostasis during diagnostic and interventional endovascular procedures.

The Early Bird provides physicians with an early indication of a potential internal bleeding complication by initial detection and monitoring of extravascular fluid accumulation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary for the Saranas® Early Bird® Bleed Monitoring System

Contact Information

Manufacturer Name

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Official Contact

Odell Roberts
Quality Director

Consultant

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510(k) Summary prepared on April 21, 2023

Regulatory Information

FDA identifies this generic type of device as:

> Intravascular bleed monitor. An intravascular bleed monitor is a probe, catheter, or catheter introducer that measures changes in bioimpedance and uses an algorithm to detect or monitor progression of potential internal bleed complications.

Regulation Number: 21 CFR 870.1345

Classification: II

Product Code: QFJ

Device Trade/Proprietary Name: Saranas® Early Bird® Bleed Monitoring System

Claim of Equivalence

Traditional 510(k) claiming equivalence to legally marketed device of same name:

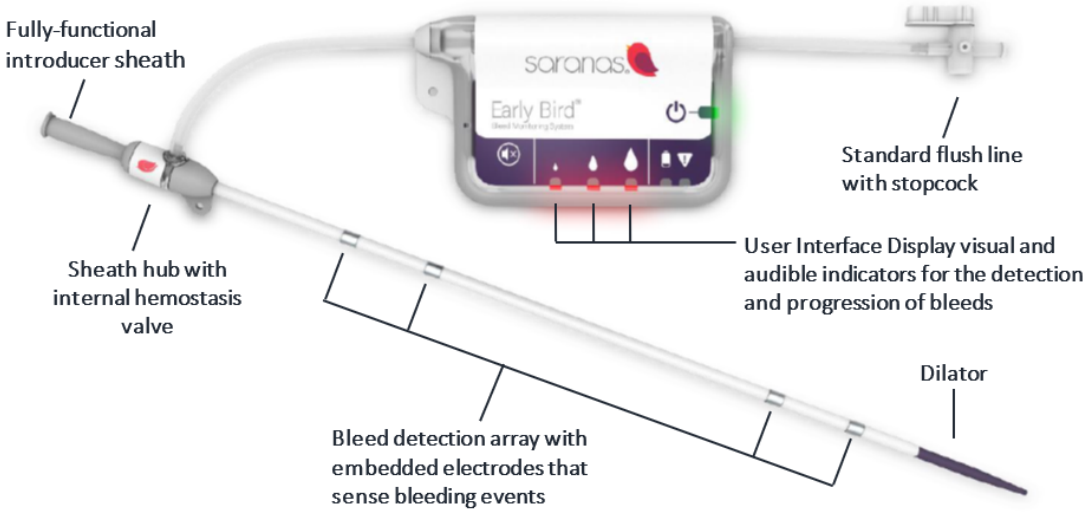
> Saranas® Early Bird® Bleed Monitoring System *DE NOVO* Submission Number: DEN180021
>
> Date *DE NOVO* Classification Granted: March 1, 2019

Device Description

The Saranas Early Bird Bleed Monitoring System (Early Bird) is a single use, disposable, Ethylene Oxide sterilized medical device. The Early Bird now claims a 2-year shelf life.

The Early Bird consists of the following: introducer sheath, user interface display (UID), for the early detection and monitoring of potential internal bleeding complications (IBCs), and a compatible dilator as shown in Figure 1.

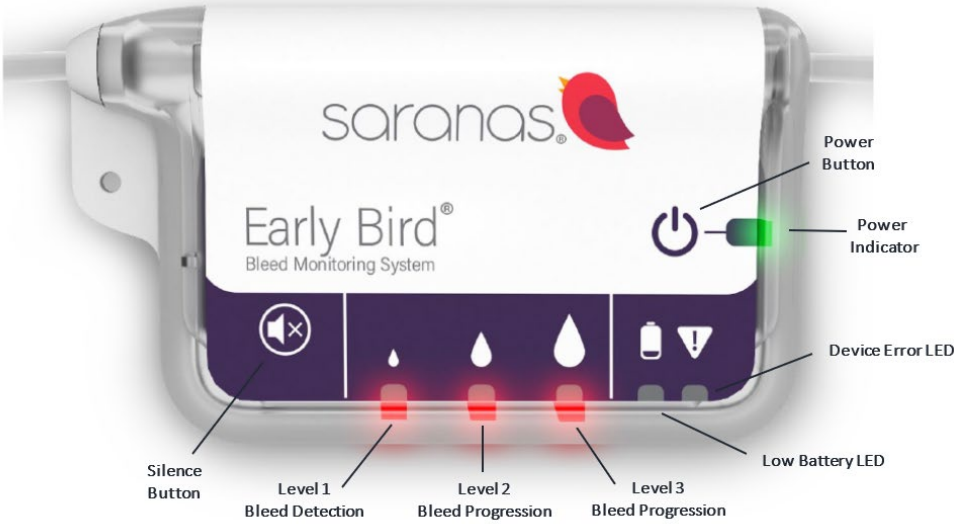
FIGURE 1: Early Bird Bleed Monitoring System



The Early Bird introducer sheath contains four embedded electrodes on the cannula and a hemostasis valve located within the sheath hub. The distal end of the sheath has a tapered leading edge which transitions smoothly to the tapered dilator, forming an atraumatic device. The dilator is radiopaque to aid in visibility under fluoroscopy during insertion.

The Early Bird electrodes are connected via conductors, which transverse an independent lumen in the flush line, to a battery powered impedance analyzer, which resides in the User Interface Display (UID), depicted in Figure 2. The Early Bird is designed to monitor changes in bioimpedance due to extravascular fluid accumulation in the region where the device is inserted into the body during a percutaneous endovascular procedure.

FIGURE 2: Early Bird User Interface Display



Indications for Use

The Early Bird is indicated for the introduction of catheters, catheter balloons, and other diagnostic and interventional devices into the femoral artery or femoral vein while maintaining hemostasis during diagnostic and interventional endovascular procedures.

The Early Bird provides physicians with an early indication of a potential internal bleeding complication by initial detection and monitoring of extravascular fluid accumulation.

Summary of Device Instructions for Use (IFU) Changes

- A clarification was added to one device warning because of firmware changes.
- Sheath preparation directions for use included additional information:
    - The device is activated by pulling on the battery isolation pull tab before it is inserted into a patient for use and turned off after confirming a blinking green light.
    - The device is reactivated by pressing the power button after the device is inserted into the patient.
- Early Bird bioimpedance measurement reset functionality directions for use were added:
    - Briefly, at the physician's discretion, pressing the power button for seven (7) seconds, anytime five (5) minutes after activation, initiates the reset action as indicated by all three Bleed Monitoring Indicators (red LEDs) flashing once per second.
    - A successful reset is confirmed by all indicators flashing once and a brief audible tone identical to the power on sequence of the predicate and modified device (i.e., power on sequence unchanged).

Technological Characteristics of Modified Device Versus Predicate Device

Some internal bleeding complications may progress slowly resulting in a rate of change of bioimpedance lower than the existing Early Bird Bleed Monitoring System (EBBMS) device's slope threshold. As a result, these slower bleeds may go undetected. This software release augments the detection algorithm by integrating an additional detection scheme based on an impedance drop threshold to supplement the current detection algorithm. The enhanced algorithm triggers a Level 1 bleed detection upon either an impedance drop threshold from a baseline impedance value or a bioimpedance drop rate that exceeds a slope threshold: the later trigger criterion being identical to the predicate device trigger criterion. Once the Level 1 bleed is activated by either detection scheme, the Level 2 and Level 3 detections function the same as in the predicate version of the firmware.

The modified device has an improved power on self-test upon activation, which allows for confirming the functional health of the device with a reduction of false error indications. Specifically, the upper limit of the calibration self-check was widened to reduce erroneous faults after activation. The enhanced firmware also provides an opportunity for users to reset the EBBMS detection algorithm at their discretion. Resetting the device is equivalent to activating a new device, reestablishing the bioimpedance baseline and enables further bleed detection and monitoring. The physical Early Bird device is unchanged from the firmware update. There are no changes to device materials or dimensions. There are no hardware changes to the Early Bird device related to the update of the firmware.

Below is a table that summarizes the technological characteristics of the device in this K230273 submission and compares these technological characteristics to the legally marketed Early Bird Bleed Monitoring System (DEN180021).

	Subject Device (K230273)	**Predicate Device (DEN180021)**	**Rationale for Substantial Equivalence (SE)**
Sponsor	Saranas, Inc.	Saranas, Inc.	No change
Device Name	Saranas® Early Bird® Bleed Monitoring System	Saranas® Early Bird® Bleed Monitoring System	No change
Device Regulation / Classification Name	21 CFR 870.1345 Intravascular Bleed Monitor	21 CFR 870.1345 Intravascular Bleed Monitor	No change
Product Code / Class	QFJ / Class II	QFJ / Class II	No change
Indications for Use	The Early Bird is indicated for the introduction of catheters, catheter balloons, and other diagnostic and interventional devices into the femoral artery or femoral vein while maintaining hemostasis during diagnostic and interventional endovascular procedures. The Early Bird provides physicians with an early indication of a potential internal bleeding complication by initial detection and monitoring of extravascular fluid accumulation.	The Early Bird is indicated for the introduction of catheters, catheter balloons, and other diagnostic and interventional devices into the femoral artery or femoral vein while maintaining hemostasis during diagnostic and interventional endovascular procedures. The Early Bird provides physicians with an early indication of a potential internal bleeding complication by initial detection and monitoring of extravascular fluid accumulation.	No change
Intended Use	The Early Bird is intended: • to be inserted into the femoral artery or femoral vein to provide a conduit for the insertion of diagnostic and interventional endovascular devices. • to provide physicians with an early indication of extravascular fluid accumulation, which may be due to a potential internal bleeding complication. • to detect and monitor changes in bioimpedance due to extravascular fluid accumulation, and to provide physicians with indications that a potential internal bleeding complication is progressing. The Early Bird is intended to provide physicians and other healthcare providers with additional information to aid in their clinical assessment of the patient during and after endovascular procedures. As such, it is not intended to diagnose or replace clinical judgment of healthcare professionals.	The Early Bird is intended: • to be inserted into the femoral artery or femoral vein to provide a conduit for the insertion of diagnostic and interventional endovascular devices. • to provide physicians with an early indication of extravascular fluid accumulation, which may be due to a potential internal bleeding complication. • to detect and monitor changes in bioimpedance due to extravascular fluid accumulation, and to provide physicians with indications that a potential internal bleeding complication is progressing. The Early Bird is intended to provide physicians and other healthcare providers with additional information to aid in their clinical assessment of the patient during and after endovascular procedures. As such, it is not intended to diagnose or replace clinical judgment of healthcare professionals.	No change
Shelf Life	2 years	1 year	Two-year real time aging and two-year accelerated aging validation studies, conducted in compliance with applicable ISO and ASTM standards, verified that packaging and sterile barrier requirements, electrical performance requirements, and mechanical performance requirements were all met, demonstrating equivalent performance to the predicate device.
Device Sizes	6 French and 8 French	6 French and 8 French	No change

	Subject Device (K230273)	Predicate Device (DEN180021)	Rationale for Substantial Equivalence (SE)
Device Working Length (with dilator)	20 cm (23 cm)	20 cm (23 cm)	No change
Single-Use Device?	Yes	Yes	No change
Sterilization Method	Ethylene Oxide; SAL 10^{-6}	Ethylene Oxide; SAL 10^{-6}	No change
Power Source	1 Alkaline 1.5V AAA battery	1 Alkaline 1.5V AAA battery	No change
Battery Life	Up to 12 hours	Up to 12 hours	No change
Electrical Safety	ME Equipment Class: Internally Powered Patient Connection: Type BF	ME Equipment Class: Internally Powered Patient Connection: Type BF	No change
Initial Device Activation	User interface display battery pull tab	User interface display battery pull tab	No change
Internal Bleeding Complication (IBC) Indicators	Audible and Visual indicators (three levels)	Audible and Visual indicators (three levels)	No change
Software Verification and Validation Requirements Met?	Yes	Yes	The subject device does not introduce any new concerns for safety or effectiveness with the firmware changes. The subject device and the predicate device demonstrated to be substantially equivalent.
Ability for device to be reset?	Yes	No	The reset allows the clinician to initiate a new, real-time bleed monitoring session to account for situations involving active bleeding, or when the device becomes accidentally dislodged. The reset restores the device to the original factory settings. There is no change to the impedance measurement mechanism or the IBC indicators, and therefore, the subject device and the predicate device demonstrate to be substantially equivalent.
Direct Contact Biocompatibility Testing	Meets ISO 10993	Meets ISO 10993	No change

Non-clinical Performance Data

Design controls were conducted in accordance with IEC 62304:2006, ISO 13485:2016, 21 CFR Part 820 and ISO 14971:2019. Design verification activities centered around existing Early Bird software and electrical verification test protocols and acceptance criteria (e.g., for the User Interface Display, Printed Circuit Board Assembly, and non-product tool data processor), and design validation activities centered around existing data sets from the Early Bird animal validation study. Verification and validation results all passed, indicating that the enhanced algorithm provides an alternate Level 1 bleed detection which triggers upon an impedance drop threshold from a baseline impedance value. These design control activities demonstrate reliable results and risk controls that form the basis for substantial equivalence between the designs of the modified Early Bird and the cleared Early Bird (DEN180021).

Conclusions

Risk analysis and assessment were conducted in accordance with ISO 13485:2016 and ISO 14971:2019. In summary, there were no unacceptable risks due to device operation because of the algorithm changes.

The device algorithm change does not change existing device precautions, potential adverse events, and the essential performance statement within the Device Instructions for Use. Early Bird risk management documentation (hazards, failure modes, and effects analyses) was updated accordingly.

Possible device failure risk hazards have been mitigated through design verification and validation activities, and therefore, the risk level of possible device failure did not change.

The software design verification and validation activities and regression testing provide a high degree of assurance for safety and effectiveness that the device performs as intended. These design controls demonstrate reliable results and risk controls that form the basis for substantial equivalence between the designs of the modified Early Bird and the cleared Early Bird (DEN180021).