



March 1, 2019

Saranas, Inc.
% Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2834 Hawthorn St.
San Diego, California 92104

Re: DEN180021
Trade/Device Name: Early Bird Bleed Monitoring System
Regulation Number: 21 CFR 870.1345
Regulation Name: Intravascular bleed monitor
Regulatory Class: Class II
Product Code: QFJ
Dated: April 20, 2018
Received: April 23, 2018

Dear Allison Komiyama:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Early Bird Bleed Monitoring System, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Early Bird Bleed Monitoring System, and substantially equivalent devices of this generic type, into Class II under the generic name intravascular bleed monitor.

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 bleeding complications.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE)

determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 23, 2018, FDA received your De Novo requesting classification of the Early Bird Bleed Monitoring System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Early Bird Bleed Monitoring System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Early Bird Bleed Monitoring System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Pyrogenicity testing Shelf-life testing Labeling
Blood loss, bleeding, hematoma	Human factors testing Labeling Animal performance testing Non-clinical performance testing
Embolization (micro or macro) with transient or permanent ischemia	Human factors testing Labeling Animal performance testing Non-clinical performance testing
Vascular trauma (i.e., dissection, rupture, perforation, tear, etc.)	Human factors testing Labeling Animal performance testing Non-clinical performance testing
Electrical shock	Electrical safety testing
Device failure due to interference with other devices	Electromagnetic compatibility (EMC) testing Electrical safety testing
Device failure due to software malfunction	Software verification, validation, and hazard analysis

In combination with the general controls of the FD&C Act, the intravascular bleed monitor is subject to the following special controls:

- (1) *In vivo* animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use and evaluate the following:
 - (i) Device performance characteristics;
 - (ii) Adverse effects, including gross necropsy and histopathology; and
 - (iii) Device usability, including device preparation, device handling, and user interface.
- (2) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - (i) Tensile testing of joints and materials;
 - (ii) Mechanical integrity testing;
 - (iii) Friction testing;
 - (iv) Flush testing;
 - (v) Air leakage and liquid leakage testing;
 - (vi) Latching and unlatching testing;
 - (vii) Kink and bend testing;
 - (viii) Insertion force testing;
 - (ix) Torque testing;
 - (x) Corrosion testing; and
 - (xi) Dimensional tolerance testing.
- (3) Performance data must support the sterility and pyrogenicity of the device components intended to be provided sterile.
- (4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
- (5) The patient contacting components of the device must be demonstrated to be biocompatible.
- (6) Software verification, validation, and hazard analysis must be performed.
- (7) Performance data must demonstrate electromagnetic compatibility (EMC), electrical safety, thermal safety, and mechanical safety.
- (8) Human factors performance evaluation must demonstrate that the user can correctly use the device, based solely on reading the directions for use.
- (9) Labeling must include:
 - (i) Instructions for use;
 - (ii) A shelf life and storage conditions;
 - (iii) Compatible procedures;
 - (iv) A sizing table; and
 - (v) Quantification of blood detected.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a

premarket notification containing information on the intravascular bleed monitor they intend to market prior to marketing the device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Bradley Quinn at 301-796-5575.

Sincerely,

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health