January 11, 2024

Stryker Instruments
Ms. Patti Arndt
Principal Specialist, Regulatory Affairs
1941 Stryker Way
Portage, Michigan 49002

Re: K232250
Trade/Device Name: SurgiCount+ System
Regulation Number: 21 CFR 880.2750
Regulation Name: Image Processing Device For Estimation Of External Blood Loss
Regulatory Class: Class II
Product Code: PBZ
Dated: July 28, 2023
Received: November 13, 2023

Dear Ms. Arndt:

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.01.11 09:52:45 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K232250

Device Name
SurgiCount+ System

Indications for Use *(Describe)*

The SurgiCount+ System Software is a multifunctional software application intended to be used as an adjunct in the estimation of blood loss and management of surgical sponges and other absorbent items. The system incorporates three distinct software configurations: Triton AI, SC+ Sponge Counting, and Triton QBL. Additionally, combined workflows (SC+ AI and SC+QBL) are provided for use in clinical environments that require both the tracking of absorbent surgical items and estimation of patient blood loss.

The Triton AI configuration is intended to be used with surgical sponges, software, hardware and accessory devices that have been validated for use with the application to estimate the hemoglobin (Hb) mass contained on used surgical sponges. The configuration is also intended to calculate an estimate of blood volume on used surgical sponges from the estimated Hb mass and a user-entered patient Hb value. The validated surgical sponges, hardware, software, accessory devices and Hb mass ranges are listed in the Instructions for Use.

The SC+ Sponge Counting configuration is intended for use as an adjunctive technology for augmenting the manual process of counting, displaying and recording the number of RFID-tagged absorbent articles used during surgical procedures, and providing a non-invasive means of locating RFID-tagged absorbent articles within an operating room and surgical sites.

The Triton QBL (Quantification of Blood Loss) configuration is intended to be used to record the weight of used surgical sponges and other absorbent items in order to calculate the quantity of fluid volume on the sponges/absorbent items.

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

I. Submitter

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II. Contact Person

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Date Prepared: January 9, 2024

III. Device

Name of Device:	SurgiCount+ System
Common or Usual Name:	External Blood Loss Estimation System
Classification Name:	Image Processing Device for Estimation of External Blood Loss (21 CFR 880.2750)
Regulatory Class:	II
Product Code:	PBZ

IV. Predicate Device

Pixel 3 Sponge System
K163507

The predicate device has not been subject to a design related recall.
No reference devices were used in this submission.

V. Device Description

The SurgiCount+ [SC+] System Software is a multi-functional software application that is intended to be used as an adjunct in the estimation of blood loss and management of surgical sponges and other surgical substrates. The system incorporates three distinct software configurations: Triton AI, SC+ Sponge Counting, and Triton Quantitative Blood Loss [QBL]. Additionally, combined workflows (SC+AI and SC+QBL) are provided for

use in clinical environments that require both the tracking of absorbent surgical items and estimation of patient blood loss. Two of the five software configurations (Triton AI and SC+AI) are Class II functions. The remaining configurations are Class I functions.

The Class II Triton AI software configuration estimates the hemoglobin (Hb) mass contained on used surgical sponges using an AI algorithm that analyzes the image of each sponge. It also calculates an estimate of blood volume on used surgical sponges from the estimated Hb mass and a user-entered patient Hb value. The Triton AI software configuration's sponge counting functionality has been modified to enhance the product's surgical sponge counting/management functionality, compared to the predicate device. New workflow steps allow users to scan, identify, and count RFID-tagged surgical sponges and other absorbent items, and to locate missing surgical sponges inside the operating room and, noninvasively, in surgical sites.

The SaMD product includes the following nonmedical device and Class I consumable and hardware accessories: a mobile device (Apple iPad Pro), RFID-tagged surgical sponges/absorbent items, an RFID reader, a bluetooth-enabled scale, and a stand (or optional wall mount) that houses the hardware accessories and connects the accessory devices to electrical power.

VI. Indications for Use

The SurgiCount+ System Software is a multifunctional software application intended to be used as an adjunct in the estimation of blood loss and management of surgical sponges and other absorbent items. The system incorporates three distinct software configurations: Triton AI, SC+ Sponge Counting, and Triton QBL. Additionally, combined workflows (SC+ AI and SC+QBL) are provided for use in clinical environments that require both the tracking of absorbent surgical items and estimation of patient blood loss.

The Triton AI configuration is intended to be used with surgical sponges, software, hardware, and accessory devices that have been validated for use with the application to estimate the hemoglobin (Hb) mass contained on used surgical sponges. The configuration is also intended to calculate an estimate of blood volume on used surgical sponges from the estimated Hb mass and a user-entered patient Hb value. The validated surgical sponges, hardware, software, accessory devices and Hb mass ranges are listed in the Instructions for Use.

The SC+ Sponge Counting configuration is intended for use as an adjunctive technology for augmenting the manual process of counting, displaying, and recording the number of RFID-tagged absorbent articles used during surgical procedures, and providing a non-invasive means of locating RFID-tagged absorbent articles within an operating room and surgical sites.

The Triton QBL (Quantification of Blood Loss) configuration is intended to be used to record the weight of used surgical sponges and other absorbent items in order to calculate the quantity of fluid volume on the sponges/absorbent items.

VII. Comparison of Technology Characteristics with the Predicate Device

The Indications for Use Statement has been updated but is unchanged with respect to its representation of the product's intended use. New indications for use (i.e., associated medical conditions/diseases/patient populations) were not proposed. The modified product remains an adjunctive technology that is intended to be used to estimate external patient blood loss and in the management of surgical sponges. Key changes include a product name change and an updated description of the modified SaMD product, neither of which impact the safety and effectiveness of the device.

Essential device functions for the SaMD product include the processing of images for the estimation of external patient blood loss and the management of surgical sponges. The SurgiCount+ System uses the same technology as the predicate device to estimate blood loss; its sponge counting functionality, however, is enhanced.

Image Processing for the Estimation of External Blood Loss: Using a qualified mobile device camera, the SaMD product instructs the user to scan/image blood-containing surgical sponges and other absorbent items used during a medical or surgical procedure. The Application then processes the images using proprietary AI Algorithms. The algorithms generate the same output for a given input (are fixed) and have been trained using machine learning techniques to recognize the sponges and to estimate Hb mass and blood loss volume on the imaged substrates.

Sponge Counting and Management: The SurgiCount+ System's sponge counting function uses ultra-high frequency (UHF) RFID technology to scan, count, and locate RFID-tagged surgical sponges. The handheld, reusable, and wireless RFID reader emits an electromagnetic field that activates items labeled with passive RFID tags within its range. The reader's firmware uses a defined communication protocol, and its antenna transmits RF energy between 902-928 MHz. The Application collects and manages the data received from the reader. By comparing the RFID-tagged absorbent articles "counted in" to a surgical procedure to the articles "counted out," the Application is able to display the number and identity of any missing absorbent articles. The predicate software system "counts" sponges by displaying the number of sponges imaged by the device for the primary purpose of blood loss estimation.

The predicate and subject devices are identical with respect to their intended use and essential performance. As shown in the following table, the key difference between the two devices is the augmentation of the predicate system's sponge counting and management functionality.

Key Feature/ Characteristic	**Predicate Device Pixel 3 Sponge System (K163507)**	**Subject Device SurgiCount+ System (K232250)**	**Comparison**
Product Type:	SaMD Product	SaMD Product	Same
Intended Use:	Image-based estimation of external patient blood loss and surgical sponge management	Image-based estimation of external patient blood loss and surgical sponge management	Same
Clinical Workflows	Single Workflow	Multifunctional Software Device with Five Workflows	Same Predicate device functionality is replicated or augmented in the modified device (Triton AI and SC+AI Workflows).
Essential Function	Estimation of Hb/Blood Volume on Imaged Surgical Sponges	Estimation of Hb/Blood Volume on Imaged Surgical Sponges	Same The incorporated AI Algorithm is identical across the two systems. The subject device meets the same accuracy specification as developed and required for the predicate system.

Key Feature/ Characteristic	**Predicate Device Pixel 3 Sponge System (K163507)**	**Subject Device SurgiCount+ System (K232250)**	**Comparison**
Implementation of Sponge Counting/Management Functionality	Device counts and displays the number of imaged sponges	System uses RFID-tagged surgical substrates and an RFID bar code reader to count/manage and locate surgical sponges	Similar Modifications augment/enhance the basic sponge counting functionality provided by the predicate system

VIII. Performance Data

Extensive software verification and validation activities were completed for the SurgiCount+ System. All test cases passed and fully traced to the product's Risk Analysis and Software Design Specification. Unit, regression, and system-level testing also was conducted and confirmed that the software functioned as designed. Cybersecurity design planning and testing ensured that the software was architected and designed to minimize cybersecurity threats.

Non-clinical (bench) testing was conducted to validate the performance of the SurgiCount+ System and demonstrated compliance with the product's Special Controls.

(1) Hemoglobin (Hb) Algorithm Performance Validation

Testing was conducted to evaluate the accuracy of the Hb algorithm in estimating the Hb mass on surgical sponges, compared to the known Hb mass on each sponge as determined by a reference assay. It was shown that the limits of agreement between the actual hemoglobin mass and sHbL measured by the SurgiCount+ software fell within the acceptance limit of ±1.99 g Hb.

(2) Sponge Recognition Algorithm (SRA) Performance Validation

Test results demonstrated that the SRA had a failure rate (sum of false images and failed detection) of 0.19%, when used to detect a representative 18x18 inch sponge type. This was well below the acceptance criterion of less than or equal to 6.5%.

(3) Electromagnetic Compatibility (EMC)Testing

The SurgiCount+ System conforms with IEC 60601-1-2 and demonstrates electromagnetic compatibility (EMC) safety and effectiveness in the hospital environment.

(4) Wireless Coexistence Testing

Wireless coexistence testing was conducted on the system in accordance with ANSI C63.27 and AAMI TIR 69. The SurgiCount+ System functioned as designed in the presence of Wi-Fi and Bluetooth interferers that were no closer than 30 cm away from the SurgiCount+ System's iPad.

(5) Human Factors Validation

Fifteen nurses participated in a complete, end-to-end, usability validation of the SurgiCount+ System. The validation study included the SurgiCount+ System's critical tasks and use scenarios, the facilitators' evaluation of the users' performance working through clinically realistic scenarios, users' input on usability and safety of the system, and residual use-error risk analysis. The validation study concluded that the SurgiCount+ System is reasonably safe and effective for its intended users and use environment and that all use risks were effectively mitigated. No significant residual or new usability risks were found.

IX. Conclusions

The SurgiCount+ System has the same intended use as the predicate Triton Sponge System. Both the subject and predicate devices are used to estimate blood loss on used surgical sponges and to count/manage surgical substrates. The SurgiCount+ System shares the same technological characteristics as the predicate device and includes new UFH RFID technology that enhances the product's ability to identify, count, and locate surgical sponges. Software and non-clinical performance testing raised no new questions of safety or effectiveness and support the substantial equivalence of the modified device to its legally marketed predicate.