March 16, 2026

Stryker Instruments
Michael Mazelin
Senior Staff Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K252282
Trade/Device Name: SurgiCount+ System
Regulation Number: 21 CFR 880.2750
Regulation Name: Image Processing Device For of External Blood Loss
Regulatory Class: II
Product Code: PBZ
Dated: February 12, 2026
Received: February 13, 2026

Dear Michael Mazelin:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252282

Device Name
SurgiCount+ System

Indications for Use *(Describe)*
The SurgiCount+ System Software is a multi-functional software application intended to be used as an adjunct in the estimation of blood loss and management of surgical sponges and other absorbent items in operating and recovery rooms, procedure rooms, and surgical centers. 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 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.

510(k) Summary – K252282

807.92(a)(1) – Submitter Information	
510(k) Submitter:	Stryker Instruments 1941 Stryker Way Portage, MI 49002 USA
Contact Information:	Michael Mazelin Sr. Staff Regulatory Affairs Specialist Stryker Instruments 1941 Stryker Way Portage, MI 49002 269-369-1909
Date Summary Prepared:	March 13, 2026

807.92(a)(2) – Name of Device	
Trade Name(s):	SurgiCount+ System
Common Name:	External Blood Loss Estimation System
Regulation Name:	Image Processing Device for Estimation of External Blood Loss
Regulation Number:	21 CFR §880.2750
Device Class:	II
Product Code(s):	PBZ

807.92(a)(3) – Predicate Device
SurgiCount+ System – K232250 The predicate device has not been subject to a design-related recall.
807.92(a)(4) – Device Description
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 in operating and recovery rooms, procedure rooms, and surgical centers. 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 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. 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 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.

807.92(a)(5) – Intended Use/Indications for Use of the Device

The SurgiCount+ System Software is a multi-functional software application intended to be used as an adjunct in the estimation of blood loss and management of surgical sponges and other absorbent items in operating and recovery rooms, procedure rooms, and surgical centers. 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 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.

807.92(a)(5) – Indications for Use Comparison

The Indications for Use Statement has been updated to specify the general environments of use, and the intended use of the subject device as compared to the predicate device remains the same (i.e., 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 the clarification of the general environments of use (i.e., operating and recovery rooms, procedure rooms, and surgical centers), which does not raise different questions of safety and effectiveness as compared to the predicate device.

807.92(a)(6) Summary of the Technological Characteristics of the Device Compared to the Predicate Device

The subject and predicate device have identical technological characteristics, and there have been no changes to the design, software, and fundamental scientific technology.

807.92(b)(1) – Nonclinical Testing to Support Submission

The function and performance of the subject device was leveraged from the predicate device through non-clinical design verification and validation testing in conjunction with risk assessment.

The results demonstrate that the subject device successfully meets the requirements of its intended use.

807.92(b)(2) – Clinical Testing

No clinical testing was provided to support this submission.

807.92(b)(3) – Conclusions Drawn from Testing Performed
The subject device, in comparison with the legally marketed predicate device, has the same design, software, and fundamental scientific technology. Verification and Validation testing and Risk assessment leveraged from the predicate device demonstrates that the device is as safe and effective as the predicate device.

Conclusion:
The information presented above demonstrates that the SurgiCount+ System is as safe and effective as the predicate device and supports a determination of substantial equivalence.