DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 5, 2016

Gauss Surgical Inc.
Ms. Artie Kaushik
Manager, RA/QA
334 State Street
Suite 201
Los Altos, California 94022

Re: K160338
Trade/Device Name: Triton 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: February 29, 2016
Received: March 2, 2016

Dear Ms. Kaushik:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160338

Device Name
Triton System

Indications for Use *(Describe)*
The Triton System is a software application intended to be used as an adjunct in the estimation of blood loss and management of surgical sponges.

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

The Triton System is also indicated for use to aid in counting surgical sponges and may be used to record and display case-specific blood components infused over time. The Triton System is additionally indicated for use to aid in managing surgical sponges, including providing a visual record of sponge images, and to record the user-entered weight of used surgical sponges in order to calculate an estimate of fluid volume on the sponges.

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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for Triton System

Submitter	Gauss Surgical Inc.
Submitter's Address	334 State Street, Suite 201 Los Altos, CA 94022
Telephone	(650) 949 4153
Fax	(650) 887 0461
Contact Person	Ms. Artie Kaushik
Date Prepared	May 04, 2016
Device Trade Name	Triton System
Device Common Name	Image processing device for estimation of external blood loss
Device Classification Name and Description	Image processing device for estimation of external blood loss: An image processing device for estimation of external blood loss is a device to be used as an aid in estimation of patient external blood loss. The device may include software and/or hardware that is used to process images capturing externally lost blood to estimate the hemoglobin mass and/or the blood volume present in the images.
Regulation Number	21 CFR 880.2750
Device Classification	Class II
Product Code	PBZ
Predicate Device Information	Pixel 3 System, K130190/DEN130015, 9 May 2014 Triton Canister System , K142801 (Reference Device)

Summary of substantial equivalence	The purpose of this notification is to: -Allow the Gauss Image Processing Device for the Estimation of External Blood Loss cleared under K130190/DEN130015 which estimated blood loss on sponges to also report information from our Image Processing Device for the Estimation of External Blood Loss cleared under K142801 which estimated blood loss in canisters (Triton Canister System). In this way, clinicians can look to only one screen to see a blood loss estimate which includes sponges and canisters -Update the option for recording user estimated blood loss values (in cases where the app cannot make the estimate e.g. oversaturated sponges) to provide a specific EBL range that takes into account the particular sponge type's fluid holding capacity -Include a View-Only Mode on the App to allow read-only monitoring of EBL events (including sponge, canister and other) -Allow usage of additional validated sponge types -Allow usage of validated non-square sponges -Allow usage of additional validated Bluetooth foot pedal The design, fundamental scientific technology, intended use and features of the new version of Triton System are substantially equivalent with regard to those features in the predicate device: the Pixel 3 System K 130190/DEN130015, May 13, 2014.
Device description	The Triton System is a software program (mobile medical application) used on an Apple iPad® tablet to capture images of used surgical sponges to assist surgical personnel in the management of surgical sponges after surgical use and to aid in the estimation of blood loss.

Indications for Use

The Triton System is a software application intended to be used as an adjunct in the estimation of blood loss and management of surgical sponges.

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

The Triton System is also indicated for use to aid in counting surgical sponges and may be used to record and display case-specific blood components infused over time. The Triton System is additionally indicated for use to aid in managing surgical sponges, including providing a visual record of sponge images, and to record the user-entered weight of used surgical sponges in order to calculate an estimate of fluid volume on the sponges.

Special Controls (for Image Processing Device for Estimation of External Blood Loss)	1. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Demonstration of the performance characteristics must include a comparison to a scientifically valid alternative method for measuring deposited hemoglobin mass. The following use conditions must be tested: A. Lighting conditions; B. Range of expected hemoglobin concentrations; C. Range of expected blood volume absorption; and D. Presence of other non-sanguineous fluids (e.g., saline irrigation fluid) *There is no change to the performance data of the product with the device modifications subject to this submission. Therefore previous non clinical testing validate that device performs as intended under anticipated conditions of use.* 2. Human factors testing and analysis must validate that the device design and labeling are sufficient for appropriate use by intended users of the device. *Human factors testing and analysis validate the device design and labeling are appropriate for use by intended users of device.* 3. Appropriate analysis and non-clinical testing must validate the electromagnetic compatibility (EMC) and wireless performance of the device. *No modifications made to the device that would change EMC compatibility or wireless performance of device.* 4. Appropriate software verification, validation and hazard analysis must be performed. *Software verification and hazard analysis was performed.* 5. Software display must include an estimate of the cumulative error associated with estimated blood loss values. *An estimate of the cumulative error associated with blood loss values is displayed to the user with each estimated hemoglobin mass and blood loss value. The Bland-Altman methods inform the look-up tables and resultant values displayed on the user interface each time the Triton System is used for the estimation of hemoglobin mass and blood volume loss.* 6. Labeling must include: A. Warnings, cautions, and limitations needed for safe use of the device; B. A detailed summary of the performance testing pertinent to use of the device, including a description of the bias and variance the device exhibited during testing; C. The validated surgical materials, range of hemoglobin mass, software, hardware, and accessories that the device is intended to be used with; and D. EMC and wireless technology instructions, information, and precautions *Labeling includes all details as required by the special controls.*

Summary of Performance Data and Rationale for Substantial Equivalence	Triton System was evaluated in accordance with Gauss Surgical's design controls process and risk management procedure. No new unacceptable risks were identified based on the changes incorporated into the software revision. Verification testing has been completed. No new safety or effectiveness issues were raised during the testing program. Triton System passed all verification. The results of the verification testing demonstrate that Triton meets established acceptance criteria and performs in a manner equivalent to its predicate device.
Conclusion	Triton System has the same indications for use as the predicate (Pixel 3 System). Both the subject and predicate devices are used as adjunctive tools to estimate blood loss on surgical materials. The new version shares the same technological characteristics as the predicate. Any differences between the subject and predicate devices do not raise different safety or effectiveness questions. Therefore, the devices are substantially equivalent.