DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 12, 2015

Gauss Surgical Incorporated
Ms. Peggy McLaughlin
Regulatory Consultant to Gauss Surgical
334 State Street, Suite 201
Los Altos, California 94022

Re: K142801
Trade/Device Name: Triton Canister 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 5, 2015
Received: February 10, 2015

Dear Ms. McLaughlin:

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" (21CFR 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,

Jennifer R. Stevenson -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)*

K142801

Device Name
Triton Canister System

Indications for Use *(Describe)*

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

The Triton Canister System is intended to be used with blood bearing canisters, software, hardware, and accessory items which have been validated for use with the Triton Canister System to estimate the hemoglobin (Hb) mass contained within canisters with the input of the total volume in each canister. The Triton Canister System is also intended to calculate an estimate of blood volume in blood bearing canisters from the estimated Hb mass and a user-entered patient serum Hb value. The validated canister types, hardware, software, accessory devices, and Hb mass ranges are listed in the Instructions for Use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

K142801

Section 6: 510(k) Summary (21 CFR § 807.92(c))

I. SUBMITTER INFORMATION

Submitter: Gauss Surgical, Inc.
334 State St., Suite 201
Los Altos, CA 94022

Contact: Peggy McLaughlin
Regulatory Consultant to Gauss Surgical
Phone: 650.504-8501
Email: MPMAdvisors@gmail.com

Date Summary Prepared: 9 March 2015

II. SUBJECT DEVICE INFORMATION

Device Trade Name: Gauss Surgical Triton Canister System

Common Name: Triton Canister Image Processing Device for Estimation of External Blood Loss in Surgical Canisters

Classification Name: Image Processing Device for Estimation of External Blood Loss
(21 CFR §880.2750)

Product Code: PBZ

III. PREDICATE DEVICE INFORMATION

Equivalent Devices: K130190 / DEN130015, 9 May 2014. This predicate device has not been subject to a recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Device Description:
The Gauss Surgical Triton Canister System is an image processing system to estimate the external blood lost from patients into a suction canister used to collect fluid during surgical procedures. The system is comprised of the software which runs on a mobile

platform (Apple® iPad®) and two accessories provided by Gauss Surgical, a Canister Type Specific Insert and a Canister Scanning Label. The Insert and Label ensure variables associated with imaging are standardized.

V. INDICATIONS FOR USE

Intended Use / Indications for Use:
The Triton Canister System is a software application intended to be used as an adjunct in the estimation of blood loss.

The Triton Canister System is intended to be used with blood bearing canisters, software, hardware, and accessory items which have been validated for use with the Triton Canister System to estimate the hemoglobin (Hb) mass contained within canisters with the input of the total volume in each canister. The Triton Canister System is also intended to calculate an estimate of blood volume in blood bearing canisters from the estimated Hb mass and a user-entered patient serum Hb value. The validated canister types, hardware, software, accessory devices, and Hb mass ranges are listed in the Instructions for Use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Gauss Surgical Triton Canister System is substantially equivalent to the Pixel 3 System which was cleared for commercialization via a *de novo* petition submitted by Gauss Surgical. Both systems use the same technology, namely image processing software, run on the same mobile platform to estimate blood loss in surgical procedures. The Pixel 3 System estimates blood loss on used surgical sponges and the Triton Canister System estimates blood loss in canisters used to collect aspirated fluid, both are surgical materials used in the operating room to collect fluids during surgery.

VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination and to demonstrate the Triton Canister System performs as anticipated for its intended use conditions as detailed below.

a. Electromagnetic Compatibility (EMC) and Wireless Coexistence Testing
Electromagnetic Compatibility and wireless coexistence testing as completed for Gauss Surgical's previous product and predicate, the Pixel 3 System were reviewed. The Triton Canister System uses the same iPad 2 (A1395) that was previously tested per the relevant requirements of IEC 60601-1-2:2007 Medical electrical equipment –

Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. EMC testing was conducted to meet the requirements of Class B.

Testing demonstrated that the iPad 2 is EMC compatible with the operating room environment. This testing is considered sufficient to demonstrate the electromagnetic compatibility of the iPad 2 in the surgical suite.

Wireless coexistence testing was performed, which subjected the System to increasingly noisy wireless environments and evaluation of whether essential wireless functionality performed as needed. The System (using the same iPad 2) was found to maintain essential wireless functionality under all test conditions.

Distance requirements for all interferers are noted in the Instructions for Use. The system was not tested in the presence of MRI, CT, diathermy and electromagnetic security systems such as metal detectors; this is noted in the Instructions for Use.

Therefore, this testing as provided for the Pixel 3 System continues to demonstrate electrical safety and electromagnetic compatibility of the Triton Canister System for its intended use.

The Triton Canister System App interfaces with the hardware components of the iPad 2 via standardized API's of the iOS operating system. These API's control the same hardware components specified in essential performance criteria section of the previously mentioned 60601-1-2 test of iPad 2 (i.e. WiFi, Bluetooth, touch screen, LCD screen, camera, and accelerometer). No changes have been reported in the API's used during the EMC and Wireless Coexistence testing reported previously. Since the Canister App exercises the same API's to operate these same hardware components, the testing previously performed is considered sufficient to demonstrate software compatibility with the hardware components.

This analysis and previous non-clinical testing validate the electromagnetic compatibility and wireless performance of the Triton Canister System.

b. Magnetic Resonance (MR) Compatibility

No testing has been conducted to demonstrate whether the device is MR compatible. The labeling includes a Warning that states "The device is MR Unsafe. Do not bring the device into an MR environment. The device must not be used in an MR environment."

c. Software Verification and Validation Testing

The software is considered a moderate level of concern (LOC) because inaccurate estimated blood loss may result in consequences to health. All of the elements of

software information corresponding to moderate LOC devices as outlined in FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005) were provided. Documentation describing the software development program was provided. A hazard analysis from both the patient's and user's standpoint was performed, hazards were addressed and a validation process was completed. A complete description of the Software verification and validation testing that was conducted was provided. This information included system level test protocols, pass/fail criteria and the results of these activities. A description of the cybersecurity issues involved in the control and use of the device and the mitigation of the risks arising therefrom was also provided.

This testing demonstrated the software performs as intended and all software related risks have been adequately mitigated.

d. Performance Testing Bench

Bench testing demonstrated that the Triton Canister System performs as expected under anticipated conditions of use. Bench top verification and validation studies were performed to evaluate the accuracy of the device's estimation of hemoglobin mass loss (cHbL, g) and blood volume loss (cEBL, ml) in comparison to known Hb mass and blood volume contained in used surgical canisters.

Bench top verification testing compared the ability of the Triton Canister System (including algorithm, app, server and accessories – Insert and Scanning Label) to estimate canister hemoglobin mass loss and canister blood volume loss to a scientifically valid method of estimating hemoglobin mass and blood volume contained in canisters containing fluid that would be aspirated during a surgical procedure. This testing was completed for the validated canister, Medi-Vac Guardian 3L canister, and expected conditions of use as labeled for the product. This verification protocol called out a clinically relevant acceptance criteria.

Briefly, this testing was undertaken by depositing known quantities of blood volume and Hb mass into canisters and imaging them with Triton Canister System. The canister fluid samples represented the clinically-expected ranges and distributions of fluid volume, dilution (by saline), Hb mass, hemolysis levels, ambient light illuminance, and serum patient Hb. For each canister preparation, the Triton Canister App was used to capture scans of the Canisters under the three different ambient lighting conditions to confirm the ability of the algorithm to operate consistently across a range of intraoperative ambient illuminance. User-entered volumes input into the app were recorded as well.

The images and corresponding user-entered volumes were then transferred to the server-based software, which was used to calculate hemoglobin mass (Triton cHbL) within each canister. cHbL obtained via the algorithm was then compared to the pre-measured Hb mass (Assay cHbL) of the reconstituted samples.

A plot of the association between Triton cHbL and Assay cHbL demonstrated a strong positive linear correlation between the two methods of measurement across the range of expected intraoperative conditions. Results were analyzed and benchmarked according to the acceptance criteria. A Bland-Altman analysis was performed to establish the bias and the limits of agreement between the Triton cHbL and Assay Hb mass deposited within each canister.

The bias and outer 95% CIs of the Bland-Altman Limits of Agreement fell within the pre-determined acceptance criteria.

The results of this verification testing and Bland-Altman methods inform the look-up tables and resultant “error estimate” values displayed on the user interface, each time that the Triton Canister System is used intraoperatively.

Validation testing of the Triton Canister System followed a similar protocol to Verification, demonstrating the device met the user requirements under expected conditions of use. Whole blood samples of known Hb concentration and various pre-specified volumes were reconstituted from units of human packed red blood cells and plasma. Serial dilution yielded canister samples reconstituted to ranges of fluid volume, dilution, hemolysis levels and Hb mass. For each dilution level achieved, the Triton Canister App was used to capture scans of the Canister. User-entered volumes input into the app were recorded.

The images and corresponding user-entered volumes were then transferred automatically to the server-based software via the App/Server interfaces, and the Triton Canister Algorithm automatically calculated hemoglobin mass (Triton cHbL) within each canister. The live cHbL returned to the App from the Algorithm and displayed to the user on the screen was then recorded for comparison with the Assay (pre-measured) Hb mass (Assay cHbL) of the reconstituted samples.

Similar to the verification testing, the Triton cHbL vs. Assay cHbL demonstrated a strong positive linear association between the two methods of measurement across the range of expected intraoperative conditions. The bias and outer 95% CIs of the Bland-Altman Limits of Agreement fell within the acceptance criteria.

In summary, performance data has demonstrated that the device performs as intended under anticipated conditions of use as compared to a scientifically valid alternative method for measuring deposited hemoglobin mass. The required conditions of lighting, range of expected hemoglobin concentrations, range of expected blood volume and presence of other non-sanguineous fluids were tested.

e. Human Factors Testing

The Triton Canister System software was developed to conform to the Human Interface Guidelines (HIG) as published by Apple for iPad Apps. Additionally human factors testing and analysis validated that the device design (i.e. user interface) and labeling are sufficient for appropriate use by intended users of the Triton Canister System.

A usability study was conducted to explore tasks associated with the use of the Triton Canister in a simulated setting. Both quantitative and qualitative survey data was collected and analyzed. Participants included personnel who are typically required to track blood loss during surgical procedures. All users were able to successfully complete the tasks per the protocol pass/fail criteria demonstrating the product meets applicable Human Factors requirements and customer design requirements per product specifications.

Human factors testing validated that the device design and labeling are sufficient for appropriate use by intended users of the device.

f. Labeling

Labeling has been provided which includes the special controls as called out in the *de novo* petition clearance for the predicate device. Specifically, the labeling includes:

- An appropriate prescription statement as required by 21 CFR 801.109;
- Warnings, cautions and limitations needed for safe use of the device;
- A detailed summary of the performance testing pertinent to the use of the device, including a description of the bias and variance the device exhibited during testing;

- The validated surgical materials, range of hemoglobin mass, software, hardware, and accessories that the device is intended to be used with; and
- EMC and wireless technology instructions and information.

VIII. SUMMARY OF SPECIAL CONTROLS REQUIRED FOR 21 CFR §880.2750

With the granting of Gauss Surgical's *de novo* petition for the Pixel 3 System, the FDA established special controls for products cleared under this classification. As summarized in this notification, the Triton Canister System has met the six (6) special controls as specified and detailed below in **Table 1** below.

TABLE 1: Special Controls Required For 21 CFR §880.2750

Special Control Required	Special Control Met
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)	As detailed in Section VIId above, Performance Testing Bench above and in Section 18 of this notification, performance data under anticipated conditions of use demonstrate that the Triton Canister System performs as intended. A comparison to a scientifically valid alternative method for measuring deposited hemoglobin mass was completed. The following anticipated conditions of use were tested: • Lighting Conditions • Range of expected Hemoglobin concentrations and hemolysis levels • Range of expected Blood volume absorption in canisters • Presence of other non-sanguineous fluids (e.g., saline irrigation fluid)
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.	As detailed in Section VIIe above, Human Factors Testing above and in Section 16 of this notification, human factors testing and analysis demonstrated that the Triton Canister System design and labeling are sufficient for appropriate use by intended users of the Triton Canister System.
3. Appropriate analysis and non-clinical testing must validate the electromagnetic compatibility (EMC) and wireless performance of the device.	As detailed in Section VIIa above, Electromagnetic Compatibility (EMC) and Wireless Coexistence Testing above and in Section 17 of this notification,

Special Control Required	Special Control Met
	analysis and previous non-clinical testing validate the EMC and wireless performance of the Triton Canister System.
4. Appropriate software verification, validation and hazard analysis must be performed.	As detailed in Section VIIc above, Software Verification and Validation Testing above and in Section 16 of this notification, software verification, validation and hazard analysis have been performed.
5. Software display must include an estimate of the cumulative error associated with estimated blood loss values.	As detailed in Sections VIId above, Performance Testing Bench above and in Section 18 of this notification, 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 results of verification testing and Bland-Altman methods inform the look-up tables and resultant values displayed on the user interface each time the Triton Canister 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 and information.	As detailed in Sections VIIf above, Labeling above and in Section 13 of this notification, labeling includes all details as required by the special controls.

VIII. CONCLUSIONS

The Gauss Surgical Triton Canister System has been shown to be substantially equivalent to the currently marketed predicate devices and all special controls as required for

products under this classification, image processing devices for estimation of external blood loss, have been addressed. The information included in this 510(k) submission demonstrates the same technological characteristics of Gauss Surgical's Triton Canister System as compared to the predicate device. The differences between the subject and predicate devices do not raise different types of safety or effectiveness questions.