DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 25, 2017

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

Re: K163507
Trade/Device Name: Triton Sponge 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: December 12, 2016
Received: December 14, 2016

Dear Artie 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,

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)*
K163507

Device Name
Triton Sponge System

Indications for Use *(Describe)*
The Triton Sponge 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 Sponge System is intended to be used with surgical sponges, software, hardware and accessory devices which have been validated for use with the Triton Sponge System to estimate the hemoglobin (Hb) mass contained on used surgical sponges. The Triton Sponge 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 Sponge 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 Sponge 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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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: Artie Kaushik
Manager RA/QA
Gauss Surgical, Inc.
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Email: artie@gausssurgical.com

Date Summary Prepared: March 31, 2016

II. SUBJECT DEVICE INFORMATION

Device Trade Name: Gauss Surgical Triton Sponge System

Common Name: Triton Sponge System Image Processing Device for Estimation of External Blood Loss in used surgical sponges

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

Product Code: PBZ

III. PREDICATE DEVICE INFORMATION

Equivalent Devices: **Triton System**
K160338, August 5, 2016. This predicate device has not been subject to a recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Triton Sponge 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 Sponge System is intended to be used with surgical sponges, software, hardware and accessory devices which have been validated for use with Triton Sponge System to estimate the hemoglobin (Hb) mass contained on used surgical sponges. This version of the Triton Sponge System includes 4 updates from the predicate Triton System (K160338):

Qualified new hardware accessory: Apple's iPad Pro to be used with Triton Sponge System.

Qualified new accessory for imaging sponges: Users will use a commercially available 3D IR laser depth sensor (referred to as the Natural User Interface or NUI Sensor in the submission)

that allows for automatic detection of sponges as well as a touch-free interface with the device to facilitate imaging of the sponge on Apple's iPad Pro device.

- To allow the use of the NUI Sensor with the Triton Sponge System, a new algorithm called the Sponge Recognition Algorithm (SRA) was added to the System. The SRA analyzes the depth maps provided by the NUI Sensor to determine whether or not a User is presenting a sponge for imaging.
- To allow the NUI Sensor to securely connect to the iPad Pro, NUI mounting brackets are provided to connect the NUI Sensor to the iPad Pro.

Addition of a step to include imaging a calibration placard with Triton Sponge App to normalize ambient light settings. The calibration card is provided to standardize the image of each sponge.

Updates to the Hemoglobin Algorithm to improve hemoglobin mass estimates by performing scene normalization as well as utilizing new data provided by the calibration palette and NUI Sensor.

V. INDICATIONS FOR USE

Intended Use / 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Gauss Surgical Triton Sponge System is substantially equivalent to the Triton System which was cleared for commercialization via K160338. Both systems have the same indication for use, have the same technology, namely image processing software, to estimate blood loss on used surgical sponges in surgical procedures and run on the same mobile platform to estimate blood loss in surgical procedures.
Triton Sponge System is an incremental improvement to the Triton System. The changes to the system and the rationale for change are discussed below.

ITEM NO.	CHARACTERISTIC	SUBJECT DEVICE TRITON SPONGE	PREDICATE DEVICE TRITON SYSTEM (K160338)	RATIONALE
i	**Device Manufacturer**	Gauss Surgical, Inc.	Gauss Surgical, Inc.	N/A
ii	**510(k) Clearance**	K163507	K160338	N/A
iii	**Product Code**	PBZ	PBZ	N/A
iv	**Regulatory Class**	II	II	N/A
v	**Regulatory Classification**	21 CFR § 880.2750	21 CFR § 880.2750	N/A
vi	**Regulation Name**	Image Processing Device for Estimation of External Blood Loss	Image Processing Device for Estimation of External Blood Loss	N/A
1	**Indications for Use**			
	Indications for Use Statement	The Triton Sponge 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 Sponge System is intended to be used with surgical sponges, software, hardware and accessory devices which have been validated for use with the Triton Sponge System to estimate the hemoglobin (Hb) mass	Same	No change

		contained on surgical sponges. The Triton Sponge 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.		
	Technological Characteristics			
2	**Identical Features**			
2.1	Fundamental Scientific Technology	Mobile App for use on mobile platform to estimate intraoperative Hb loss and blood loss on sponges	Same as subject device	The fundamental technology of the device remains the same. The enhancements made to the device are so the same technology may be used on the newer version of the iPad tablet. In addition, changes have been made to accommodate the new accessory for imaging the used sponges.
2.2	Principle of Operation	Using the mobile platform camera, the Triton Sponge System scans blood-containing surgical sponges, counts the sponges, and sends the images to the cloud server for processing. On the server, the image-processing algorithm estimates the Hemoglobin mass loss (sHbL) contained on the sponges and sends results back to the OR.	Same as subject device	The work flow for system operation remains unchanged.

2.3	System	A mobile App, Server, and Algorithm	Same as the subject device	The core components of the system remain unchanged. Change is to add new hardware accessories and updates to system that have been made to accommodate the functioning of the System.
2.5	Function of the Image Processing Software	App captures images and uses a visual algorithm to estimate Hb mass	Same as the subject device	Although software has been updated to accommodate the new hardware accessories, the core function of the image processing software remains unchanged.
2.6	Function of Algorithm	Calculates Hb mass and EBL. Requires user input of patient serum Hb value.	Same as the subject device	The function of the Algorithm remains the same. The only change to the Algorithm has been to include the scene normalization feature. Details below (3.4) in this table. Additionally, a Sponge Recognition Algorithm was added, to interface with the IR camera connected to the iPad and detect when a user has presented a sponge for imaging.
2.7	Function of Server	The remote “cloud” Server computer runs the Server software and algorithm. The Server software coordinates communication between the Algorithm and the App.	Same as the subject device	The function of the Server remains the same. The updates to the Server are incremental.
2.8	Validated Ranges	Validated range specific to each sponge type as listed in IFU	Same as the subject device	Validated range specific to each sponge type is confirmed using the same process as detailed in the predicate 510(k) K 160338 and the original 510(K) K 130190.
2.9	App to Server Communication	App communicates wirelessly with Gauss Surgical’s cloud-based server	Same as the subject device	No change to the app to Server communication
2.10	Estimate of	Estimated HbL and estimated EBL	Same as the subject	The display of estimated EBL and HBL errors

	Cumulative HBL and EBL Errors	errors are displayed on the App using the Bland-Altman method.	device	is a special requirement for this device category and the method of display remains the same with this update.
3	**New Features**			
3.1	Mobile Hardware	iPad Pro (A1584)	iPad 2 (A1395)	Change does not affect indications for use, fundamental scientific technology or operation. Safety and effectiveness are demonstrated through verification and validation testing. Per one of the special controls detailed for this category of devices, the iPad Pro and the Structure Sensor successfully passed EMC testing and wireless coexistence.
3.1.2	Operating System	Apple, Inc. iOS 10 or greater	Apple, Inc. iOS 5.0 and greater	The Operating System is provided by Apple. iPad Pro includes iOS 10. The system verification and validation confirm that iOS 10 with iPad Pro platform is safe and effective.
3.2	Imaging Accessories	NUI Sensor: Gauss qualified new 3D IR laser depth sensor (NUI sensor) that allows for automatic detection of sponges as well as a touch-free interface with the device to facilitate imaging of the sponge.	Foot Pedals: PageFlip Firefly Pedals and AirTurn BT-105 with 2 ATFS-2 Pedals and Pedal Board	A new accessory was qualified with the Triton Sponge System to improve usability of the device. Safety and effectiveness are demonstrated through validation testing. Since this accessory would be used in a hospital setting along with the iPad Pro, it was also tested for and passed EMC and wireless coexistence. In addition, the System Validation Testing confirmed the performance of the entire system to meet the same predetermined acceptance criteria as the predicate system. Therefore, the modified device is substantially equivalent to predicate.

3.3	Calibration Placard	Added step to calibrate using a calibration placard	New feature	The Calibration Placard was verified to be designed according to hardware requirements upon successful passing of the Hardware Verification Protocol which called out the dimensional and color requirements for the Placard. System Validation Testing confirmed the performance of the entire System (including Calibration Placard) to meet the same predetermined acceptance criteria as the predicate system.
3.4	Scene Normalization feature to Hb Algorithm	Added a scene normalization feature to normalize background settings for the sponge.	New feature	This feature was added as an incremental improvement to improve product performance. This feature when used with the Calibration Placard helps standardize each sponge image for ambient lighting conditions. This enhancement to the algorithm does not have any impact to user-facing components of the App. However, using the Calibration Placard is a new step and was included in the Human Factors Usability study. All Users were successfully able to use the Calibration Placard. In addition, the functioning of the System Validation Testing which is implemented with all the System accessories including iPad Pro and Calibration Placard confirmed the performance of the entire system to meet the same predetermined acceptance criteria as the predicate system.

VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination and to demonstrate the Triton Sponge 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 was completed for Gauss Surgical's Triton Sponge System.

iPad Pro EMC Testing: The new iPad Pro, A1584, manufactured by Apple, Inc., was 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.

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

The iPad Pro (A1584) was also tested for Wireless Coexistence by confirming the performance of the iPad Pro in the presence of other in-band emitters. The test addressed environmental specifications including co-channel and adjacent channel interference from other devices and users of the RF band to demonstrate that the iPad Pro performs properly in proximity to other RF wireless in-band sources. The iPad Pro 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.

NUI Sensor EMC testing: The new Structure Sensor (ST01) manufactured by Occipital, Inc., (i.e. "NUI Sensor") was 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.

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

Wireless Coexistence testing was not necessary for the Structure Sensor as it has no wireless functionalities or components.

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) are provided. Documentation describing the software development program are provided.

Software verification testing demonstrated that all specified requirements, including hazard mitigations for the Triton Sponge System have been fulfilled. Testing included verification of the special control to display a correct estimate of the cumulative error associated with estimated blood loss values. Verification demonstrated that this functionality displays correctly and as designed.

Validation testing, including performance and human factors validation, demonstrated that all device specifications conform with user needs and intended uses.

All 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 Sponge performs as intended under anticipated conditions of use. Bench top validation studies were performed to evaluate the accuracy of the device's estimation of hemoglobin mass loss on sponges (sHbL, g) and blood volume loss on sponges (sEBL, ml) in comparison to known Hb mass and blood volume contained on the surgical sponges.

Bench top performance validation testing confirmed the ability of the Triton Sponge to estimate sponge hemoglobin mass loss and sponge blood volume loss by comparing Triton generated results to known quantities of hemoglobin mass and blood contained on surgical sponges. Testing was performed using the new automatic imaging method (NUI Sensor) for imaging and the iPad Pro. This testing was completed for the expected conditions of use as labeled for the product. The bench-top validation performed on the system was the same protocol performed on the predicate product with the addition of testing across sponge illuminations, and used the same clinically justified acceptance criteria cleared for the predicate device.

Testing involved running the software app/system test protocol with sample specimens to ensure all specifications were met.

Briefly, this testing was undertaken by depositing known quantities of blood volume with a known Hb mass on surgical sponges and imaging them with Triton Sponge using the NUI accessory and iPad Pro. As is common in surgical procedures, saline is often also part of the fluid on these sponges and therefore known volumes of saline were added to some samples. The fluid samples represented the clinically-expected ranges and distributions of fluid volume, dilution (by saline), Hb mass, ambient light, sponge illumination, and serum patient Hb. For each sponge type, the Triton Sponge App was used to capture scans of the sponges under the three different ambient lighting conditions and sponge illuminations 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 were then transferred to the server-based hemoglobin algorithm software, which was used to calculate hemoglobin mass (Triton sHbL) for each imaged sponge. The sHbL value obtained via the algorithm for each sponge was then compared to the pre-measured Hb mass (Assay sHbL) of the samples.

A plot of the association between Triton sHbL and Assay sHbL demonstrated a strong positive linear correlation between the two methods of measurement and the predicate across the range of expected intraoperative conditions. Bland-Altman analysis demonstrated acceptable agreement between the sHbL and the pre-determined Hb mass and evaluation of the parameters via the acceptance criteria.

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

System validation testing of the Triton Sponge followed a similar protocol to performance validation, demonstrating the device met the user requirements under expected conditions of use. A mock surgical case was simulated by reconstituting whole blood samples of known Hb concentration from units of human packed red blood cells and plasma to create various pre-specified blood volumes. Serial dilution with sterile saline yielded sponge blood samples reconstituted to ranges of fluid volume, dilution, and Hb mass representative of a surgical operation. For each dilution level achieved, Triton Sponge was used to capture scans of the surgical sponges in an operating room. User-entered baseline Hb was recorded into the App. System validation testing was performed using the new automatic imaging method (NUI Sensor) and iPad Pro.

The images and corresponding user-entered volumes were then transferred automatically to the server-based software via the App/Server interfaces, and the Triton HB Algorithm automatically calculated hemoglobin mass (Triton sHbL) within each sponge type. The live sHbL 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 sHbL) of the reconstituted samples.

Triton sHbL vs. Assay sHbL demonstrated a strong positive linear association between the two methods of measurement across the range of expected intraoperative conditions. Bland-Altman analysis demonstrated acceptable agreement between the sHbL and the pre-determined Hb mass and evaluation of the parameters via the acceptance criteria.

In summary, the device was tested within the anticipated use conditions including variable lighting, range of expected patient serum hemoglobin concentrations, range of expected blood volume and the presence of other non-sanguineous fluids, and the resulting data demonstrated acceptable performance.

e. Human Factors Testing

The Triton Sponge System software was developed to conform to the Human Interface Guidelines (HIG) as published by Apple for iOS Apps. Additionally, human factors usability 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 Sponge System.

A usability study was conducted to explore critical and frequently used functions associated with the Triton Sponge System in a simulated setting using hardware (iPad Pro) and the validated accessory (NUI Sensor). 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 K160338 and in the original *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, imaging methodologies, 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 original Pixel 3 System, the FDA established special controls for products cleared under this classification. As summarized in this notification, the Triton Sponge System has met the six (6) special controls as specified and detailed below in **Table 6-1** below.

TABLE 6-1: SPECIAL CONTROLS REQUIRED FOR 12 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)	Non-clinical performance testing using the iPad Pro and the NUI sensor was conducted and demonstrated that the device performs as intended under anticipated conditions of use including expected lighting conditions, range of expected hemoglobin values, range of expected blood volume absorption and presence of other non-sanguineous fluids. Performance data under anticipated conditions of use demonstrate that the Triton Sponge System performs as intended.
2. Human factors testing and analysis must validate that the device design and labeling	Human factors testing and analysis demonstrated that the Triton Sponge

Special Control Required	Special Control Met
are sufficient for appropriate use by intended users of the device.	System, labeling, and the NUI sensor as an accessory to support scanning of images with the Triton Sponge System are sufficient for appropriate use by intended users of the Triton Sponge System.
3. Appropriate analysis and non-clinical testing must validate the electromagnetic compatibility (EMC) and wireless performance of the device.	EMC and wireless performance of the Triton Sponge System with new iPad Pro and accessory NUI Sensor have been validated.
4. Appropriate software verification, validation and hazard analysis must be performed.	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.	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 Sponge 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.	Labeling includes all details as required by the special controls.

IX. CONCLUSIONS

The Triton Sponge introduces no new indication for use and is substantially equivalent in terms of Indications for Use as the identified predicate device.

The Triton Sponge System was verified in its operating environments. Verification and validation activities related to the device modification were performed on the applicant device, and the predetermined acceptance criteria were met in all cases.

From the testing data included in this submission, it can be concluded that the Gauss Surgical Triton Sponge System his substantially equivalent to the currently marketed predicate device in indications for use, design, technological characteristics, mechanism of action and performance. In addition, all special controls as required for products under this classification, image processing devices for estimation of external blood loss, have been addressed. The differences between the subject and predicate device do not raise different types of safety or effectiveness questions.