



Food and Drug Administration
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May 9, 2014

Gauss Surgical, Inc.
c/o Peggy McLaughlin
Consulting Vice President, Regulatory Affairs
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Suite 201
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Re: K130190
Pixel 3 System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 880.2750
Regulation Name: Image processing device for estimation of external blood loss
Regulatory Classification: Class II
Product Code: PBZ
Dated: January 31, 2013
Received: February 4, 2013

Dear Ms. McLaughlin:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Pixel 3 System, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

The Pixel 3 System is a software application intended to be used as an adjunct in the estimation of blood loss and management of surgical sponges.

The Pixel 3 System is intended to be used with surgical sponges, software, hardware and accessory devices which have been validated for use with the Pixel 3 System to estimate the hemoglobin (Hb) mass contained on used surgical sponges. The Pixel 3 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 Pixel 3 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 Pixel 3 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.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Pixel 3 System, and substantially equivalent devices of this generic type, into class II under the generic name, Image processing device for estimation of external blood loss.

FDA identifies this generic type of device as:

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On February 4, 2013, FDA received your *de novo* requesting classification of the Pixel 3 System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Pixel 3 System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Pixel 3 System indicated as

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can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Failure to Provide Accurate or Precise Device Output	Non-clinical Performance Testing Software Display of Estimated Cumulative Error Software Verification, Validation, and Hazard Analysis Human Factors Testing Labeling
Use Error	Human Factors Testing Labeling
Electromagnetic Incompatibility	Electromagnetic Compatibility Testing Wireless Testing Labeling

In combination with the general controls of the FD&C Act, the Image processing device for estimation of external blood loss is subject to the following special controls:

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)

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.
3. Appropriate analysis and non-clinical testing must validate the electromagnetic compatibility (EMC) and wireless performance of the device.
4. Appropriate software verification, validation and hazard analysis must be performed.
5. Software display must include an estimate of the cumulative error associated with estimated blood loss values.
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.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Image processing application for estimation of blood loss on surgical media they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Kristy Katzenmeyer-Pleuss, Ph.D., at (301) 796-2441.

Sincerely yours,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
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