



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA-2017-N-6570]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Image Processing Device for Estimation of External Blood Loss

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the image processing device for estimation of external blood loss into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the image processing device for estimation of external blood loss' classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on May 9, 2014.

FOR FURTHER INFORMATION CONTACT: Jitendra Virani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G459, Silver Spring, MD, 20993-0002, 301-796-6398, Jitendra.Virani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the image processing device for estimation of external blood loss as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and

Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence").

Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on November 13, 2012, finding the Gauss Surgical Pixel 3 Application not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On February 4, 2013, Gauss Surgical, Inc., submitted a request for De Novo classification of the PIXEL 3 SYSTEM. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 9, 2014, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 880.2750. We have named the generic type of device image processing device for estimation of external blood loss, and it is identified as 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.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--Image Processing Device for Estimation of External Blood Loss Risks and Mitigation Measures

Identified Risks	Mitigation Measures
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; and Labeling
Use error	Human factors testing and Labeling
Electromagnetic incompatibility	Electromagnetic compatibility testing, Wireless testing, and Labeling

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910-0844; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for part 880 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 880.2750 to subpart C to read as follows:

§ 880.2750 Image processing device for estimation of external blood loss.

(a) *Identification.* 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.

(b) *Classification*. Class II (special controls). The special controls for this device are:

(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:

(i) Lighting conditions;

(ii) Range of expected hemoglobin concentrations;

(iii) Range of expected blood volume absorption; and

(iv) 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:

(i) Warnings, cautions, and limitations needed for safe use of the device;

(ii) 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;

(iii) The validated surgical materials, range of hemoglobin mass, software, hardware, and accessories that the device is intended to be used with; and

(iv) EMC and wireless technology instructions and information.

Dated: December 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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