Country	Entity	License requirement	License review policy	**Federal Register** citation
	Joint Stock Company Federal Scientific and Production Center Titan-Barrikady, a.k.a., the following three aliases: —Federal Research and Production Center Titan Barrikady JSC; —Titan Design Bureau; *and* —JSC FNPTS Titan-Barrikady. Prospekt Imeni V.I. Lenina, b/n 400071, Volgograd, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	82 FR [INSERT FR PAGE NUMBER], 12/20/17.
*	*	*	*	*	*	*

Dated: December 15, 2017.

Richard E. Ashooh,

Assistant Secretary for Export Administration.

[FR Doc. 2017–27388 Filed 12–19–17; 8:45 am]

BILLING CODE 3510–33–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 December 20, 2017. 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, 360*l,* 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.

[FR Doc. 2017–27443 Filed 12–19–17; 8:45 am]

BILLING CODE 4164–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Valuation of Benefits and Assets; Expected Retirement Age

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This rule amends the Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans by substituting a new table for determining expected retirement ages for participants in pension plans undergoing distress or involuntary termination with valuation dates falling in 2018. This table is needed to compute the value of early retirement benefits and, thus, the total value of benefits under a plan.

DATES: This rule is effective January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Hilary Duke (*duke.hilary@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, 202–326–4400 ext. 3839. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4400 ext. 3839.)

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation (PBGC) administers the pension plan termination insurance program under Title IV of the Employee Retirement Income Security Act of 1974 (ERISA). PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) sets forth (in subpart B) the methods for valuing plan benefits of terminating single-employer plans covered under Title IV. Guaranteed benefits and benefit liabilities under a plan that is undergoing a distress termination must be valued in accordance with subpart B of part 4044. In addition, when PBGC terminates an underfunded plan involuntarily pursuant to ERISA section 4042(a), it uses the subpart B valuation rules to determine the amount of the plan's underfunding.

Under § 4044.51(b) of the asset allocation regulation, early retirement benefits are valued based on the annuity starting date, if a retirement date has been selected, or the expected retirement age, if the annuity starting date is not known on the valuation date. Sections 4044.55 through 4044.57 set forth rules for determining the expected retirement ages for plan participants entitled to early retirement benefits. Appendix D of part 4044 contains tables to be used in determining the expected early retirement ages.

Table I in appendix D (Selection of Retirement Rate Category) is used to determine whether a participant has a low, medium, or high probability of retiring early. The determination is based on the year a participant would reach ''unreduced retirement age'' (*i.e.,* the earlier of the normal retirement age or the age at which an unreduced benefit is first payable) and the participant's monthly benefit at unreduced retirement age. The table applies only to plans with valuation dates in the current year and is updated annually by PBGC to reflect changes in the cost of living, etc.

Tables II–A, II–B, and II–C (Expected Retirement Ages for Individuals in the Low, Medium, and High Categories respectively) are used to determine the expected retirement age after the probability of early retirement has been determined using Table I. These tables establish, by probability category, the expected retirement age based on both the earliest age a participant could retire under the plan and the unreduced retirement age. This expected retirement age is used to compute the value of the early retirement benefit and, thus, the total value of benefits under the plan.

This document amends appendix D to replace Table I–17 with Table I–18 to provide an updated correlation, appropriate for calendar year 2018, between the amount of a participant's benefit and the probability that the participant will elect early retirement. Table I–18 will be used to value benefits in plans with valuation dates during calendar year 2018.

PBGC has determined that notice of, and public comment on, this rule are impracticable and contrary to the public interest. Plan administrators need to be able to estimate accurately the value of plan benefits as early as possible before initiating the termination process. For that purpose, if a plan has a valuation date in 2018, the plan administrator needs the updated table being promulgated in this rule. Accordingly, PBGC finds that the public interest is best served by issuing this table expeditiously, without an opportunity for notice and comment, and that good cause exists for making the table set forth in this amendment effective less than 30 days after publication to allow as much time as possible to estimate the value of plan benefits with the proper table for plans with valuation dates in early 2018.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866 and Executive Order 13771.

Because no general notice of proposed rulemaking is required for this regulation, the Regulatory Flexibility Act of 1980 does not apply (5 U.S.C. 601(2)).

List of Subjects in 29 CFR Part 4044

Employee benefit plans, Pension insurance.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 2. Appendix D to part 4044 is amended by removing Table I–17 and adding in its place Table I–18 to read as follows:

Appendix D to Part 4044—Tables Used To Determine Expected Retirement Age