

TABLE II TO PART 157—Continued

Year	Limit
1997	4,400,000
1998	4,500,000
1999	4,550,000
2000	4,650,000
2001	4,750,000
2002	4,850,000
2003	4,900,000
2004	5,000,000
2005	5,100,000
2006	5,250,000
2007	5,400,000
2008	5,550,000
2009	5,600,000
2010	5,700,000
2011	5,750,000
2012	5,850,000
2013	6,000,000
2014	6,100,000
2015	6,200,000
2016	6,300,000
2017	6,400,000
2018	6,500,000

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 878**

[Docket No. FDA-2018-N-0387]

**Medical Devices; General and Plastic Surgery Devices; Classification of the Extracorporeal Shock Wave Device for Treatment of Chronic Wounds**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the extracorporeal shock wave device for treatment of chronic wounds 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 extracorporeal shock wave device for treatment of chronic wounds' 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 March 7, 2018. The classification was applicable on December 28, 2017.

**FOR FURTHER INFORMATION CONTACT:** Mehmet Kosoglu, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1572, Silver Spring, MD 20993-0002, 301-796-6194, *Mehmet.Kosoglu@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Upon request, FDA has classified the extracorporeal shock wave device for treatment of chronic wounds 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 to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). 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 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 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**

On July 25, 2016, Sanuwave, Inc., submitted a request for De Novo classification of the dermaPACE 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 December 28, 2017, 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 878.4685. We have named the generic type of device extracorporeal shock wave device for treatment of chronic wounds, and it is identified as a prescription device that focuses acoustic shock waves onto the dermal tissue. The shock waves are

generated inside the device and transferred to the body using an acoustic interface.

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—EXTRACORPOREAL SHOCK WAVE DEVICE FOR TREATMENT OF CHRONIC WOUNDS RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction .....	Biocompatibility evaluation.
Infection .....	Reprocessing validation and Labeling.
Inadequate healing .....	Labeling.
Device failure/malfunction leading to application site injury .....	Non-clinical performance testing; Electrical safety testing; Electro-magnetic compatibility (EMC) testing; Use life testing; Software verification, validation, and hazard analysis; and Labeling.
Hearing loss .....	Non-clinical performance 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).

At the time of classification, extracorporeal shock wave devices for treatment of chronic wounds are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

**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 and guidance. 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 878**

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 878 is amended as follows:

**PART 878—GENERAL AND PLASTIC SURGERY DEVICES**

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.4685 to subpart E to read as follows:

**§ 878.4685 Extracorporeal shock wave device for treatment of chronic wounds.**

(a) *Identification.* An extracorporeal shock wave device for treatment of chronic wounds is a prescription device that focuses acoustic shock waves onto the dermal tissue. The shock waves are generated inside the device and

transferred to the body using an acoustic interface.

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

(1) Non-clinical performance testing must be conducted to demonstrate that the system produces anticipated and reproducible acoustic pressure shock waves.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate that the reusable components of the device can be reprocessed for subsequent use.

(4) Performance data must be provided to demonstrate the electromagnetic compatibility and electrical safety of the device.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Performance data must support the use life of the system by demonstrating continued system functionality over the labeled use life.

(7) Physician labeling must include:

(i) Information on how the device operates and the typical course of treatment;

(ii) A detailed summary of the device’s technical parameters;

(iii) Validated methods and instructions for reprocessing of any reusable components; and

(iv) Instructions for preventing hearing loss by use of hearing protection.

(8) Patient labeling must include:

(i) Relevant contraindications, warnings, precautions, adverse effects, and complications;

(ii) Information on how the device operates and the typical course of treatment;

- (iii) The probable risks and benefits associated with the use of the device;
- (iv) Post-procedure care instructions; and
- (v) Alternative treatments.

Dated: February 28, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 801

[TD 9831]

RIN 1545-BL88

#### Balanced System for Measuring Organizational and Employee Performance Within the Internal Revenue Service

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations and removal of temporary regulations.

**SUMMARY:** This document contains final regulations regarding management and personnel within the IRS. The final regulations relate to the “employee satisfaction measures” utilized by the IRS in its Balanced System for Measuring Organizational and Employee Performance. These regulations affect internal operations of the IRS and the systems employed to evaluate the performance of organizations within the IRS and individuals employed by the IRS.

**DATES:**

*Effective Date:* These regulations are effective on March 7, 2018.

*Applicability Date:* These regulations are applicable for the reporting of employee satisfaction information within the meaning of 26 CFR 801.5 that occurs on or after March 7, 2018.

**FOR FURTHER INFORMATION CONTACT:** Julie Barry, at (202) 317-5759 (not a toll free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

On November 13, 2014, the IRS published in the **Federal Register** (79 FR 67351) a temporary regulation (TD 9703) modifying the regulations governing the IRS Balanced System for Measuring Organizational and Employee Performance. A notice of proposed rulemaking (REG-138605-13) cross-referencing the temporary regulation was published in the **Federal**

**Register** (79 FR 67396) on the same day. The text of the temporary regulation served as the text of the proposed regulation.

**Summary of Comments and Explanation of Revisions**

The IRS provided an opportunity for comment and an opportunity for a public hearing. No public hearing was requested, and the IRS received one written comment. The written comment did not substantively address the proposed change, but instead expressed appreciation for the IRS’s efforts to obtain public feedback to support an open, measurable, and user-friendly government.

The regulation being modified concerns “employee satisfaction measures” and requires the collection of information from employees through various means, including employee surveys. Once collected, the information is used to measure and report on employee satisfaction, one of three elements comprising the IRS balanced performance measurement system. To be consistent with other government-wide employee satisfaction surveys, the proposed regulation provides that employee satisfaction measures can be reported at a higher agency level.

Specifically, the proposed regulation relates to the employee satisfaction measure, § 801.5, of the IRS Balanced System for Measuring Organizational and Employee Performance (26 CFR part 801). As originally implemented in 1999, the employee satisfaction measure required the IRS to gauge and report the satisfaction of employees in pay and duty status (non-seasonal employees) to the first-level supervisor organizational level, as well as to all succeeding management levels of the organization. Consequently, the IRS utilized and modified a pre-existing survey to enable the reporting of data to first-level supervisors. Other surveys, such as OPM’s Federal Employee Viewpoint Survey (FEVS), however, report employee satisfaction data to a level of agency management higher than that of the first-level supervisor. Consequently, the IRS conducted both the FEVS survey and the internal survey that complied with § 801.5. The administration of both surveys resulted in an unnecessary expenditure of funds, an undue burden on employees, and the duplication of efforts by the IRS.

The proposed regulation permits the IRS to report employee satisfaction data at higher organization levels, thereby permitting the IRS to use the FEVS and eliminate the use of its internal survey. The corresponding temporary regulation was effective on or after November 13,

2014, and expired on or before November 10, 2017. This document adopts, without modification, the proposed regulation as final and removes the corresponding temporary regulation.

**Special Analyses**

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. Because the regulation would not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply.

Pursuant to Section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding this final regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business. No comments were received from the Small Business Administration.

**Drafting Information**

The principal author of these regulations is Julie A. Barry, Office of Associate Chief Counsel (General Legal Services). However, other personnel from the Treasury Department and the IRS participated in their development.

**List of Subjects in 26 CFR Part 801**

Federal employees, Organization and functions (Government agencies).

**Adoption of Amendments to the Regulations**

Accordingly, 26 CFR part 801 is amended as follows:

**PART 801—BALANCED SYSTEM FOR MEASURING ORGANIZATIONAL AND EMPLOYEE PERFORMANCE WITHIN THE INTERNAL REVENUE SERVICE**

■ **Paragraph 1.** The authority citation for part 801 continues to read in part as follows:

**Authority:** 5 U.S.C. 9501 \* \* \*

■ **Par. 2.** Section 801.5 is revised to read as follows:

**§ 801.5 Employee satisfaction measures.**

(a) The employee satisfaction numerical ratings to be given to a Business Operating Division (BOD) or equivalent office within the IRS will be determined on the basis of information gathered through various methods. For example, questionnaires, surveys, and other information gathering mechanisms may be employed to gather data regarding satisfaction. The information