inspections and examinations in connection with preclearing passengers, crew, and their goods bound for the United States. Generally, travelers who are inspected at a preclearance facility are permitted to arrive at a U.S. domestic facility and exit the U.S. domestic terminal upon arrival or connect directly to a U.S. domestic flight without further CBP processing. Preclearance facilities primarily serve to facilitate low risk travelers, relieve passenger congestion at federal inspection facilities in the United States, and enhance security in the air environment through the screening and inspection of travelers prior to their arrival in the United States. In Fiscal Year 2010, over 14 million aircraft travelers were processed at preclearance locations. This figure represents more than 16 percent of all commercial aircraft travelers cleared by CBP in FY 2010.

The Agreement Between the Government of the United States of America and the Government of Ireland on Air Transport Preclearance was signed on November 17, 2008. Preclearance operations began in Dublin, Ireland on January 19, 2011. The Dublin preclearance station is open for use by commercial flights.

Section 101.5 of the CBP regulations (19 CFR 101.5) sets forth a list of CBP preclearance offices in foreign countries. This document amends this section to add Dublin, Ireland to the list of preclearance offices.

Inapplicability of Public Notice and Delayed Effective Date Requirements

This amendment reflects the addition of a new CBP preclearance office that was established through a signed agreement between the United States and the Government of Ireland. Accordingly, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary. For the same reason, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

The Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) do not apply. This amendment does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

Signing Authority

This document is being issued in accordance with 19 CFR 0.2(a).

List of Subjects in 19 CFR Part 101

Customs duties and inspection, Customs ports of entry, Foreign trade statistics, Imports, Organization and functions (Government agencies), Shipments, Vessels.

Amendments to Regulations

For the reasons set forth above, Part 101 of the Code of Federal Regulations (19 CFR part 101), is amended as set forth below.

PART 101—GENERAL PROVISIONS

■ 1. The general authority citation for part 101 and the specific authority citation for section 101.5 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a.

* * * * *

Section 101.5 also issued under 19 U.S.C. 1629.

* * * * *

■ 2. Revise § 101.5 to read as follows:

§ 101.5 CBP preclearance offices in foreign countries.

Listed below are the preclearance offices in foreign countries where CBP officers are located. A Director, Preclearance, located in the Office of Field Operations at CBP Headquarters, is the responsible CBP officer exercising supervisory control over all preclearance offices.

Country	CBP office
Aruba	Orangestad.
The Bahamas	Freeport.
	Nassau.
Bermuda	Kindley Field.
Canada	Calgary, Alberta.
	Edmonton, Alberta.
	Halifax, Nova Scotia.
	Montreal, Quebec.
	Ottawa, Ontario.
	Toronto, Ontario.
	Vancouver, British Columbia.
	Winnipeg, Manitoba.
Ireland	Dublin.
	Shannon.

Dated: February 11, 2011.

Alan D. Bersin,

Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2011–9883 Filed 4–22–11; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2006–N–0045] (Formerly Docket No. 2006N–0109)

Medical Devices; Reclassification of the Topical Oxygen Chamber for Extremities

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the topical oxygen chamber for extremities (TOCE) from class III to class II. This device is intended to surround a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers, such as bedsores. This reclassification is on the Secretary of Health and Human Services's own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended by the Medical Device Amendments of 1976 (the 1976 Amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities," which will serve as the special control for this device.

DATES: This rule is effective May 25, 2011.

FOR FURTHER INFORMATION CONTACT: Charles N. Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3555.

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended by the 1976 Amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and the FDAMA (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and

effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 Amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the FD&C Act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Postamendment devices remain in class III and require premarket approval, unless the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the FD&C Act (21 U.S.C. 360c(e)) governs reclassification of classified preamendments devices. This section provides that FDA may, by rulemaking, reclassify a device based upon "new information." FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term "new information," as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (*See, e.g., Holland Rantos* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (DC Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966)).

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard,* supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F. Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in "medical science." (See *Upjohn* v. *Finch,* supra, 422 F.2d at 951). Regardless of whether data before the agency are past or new data, the "new information" to support reclassification under section 513(e)(1) of the FD&C Act must be "valid scientific evidence," as defined in section 513(a)(3) of the FD&C Act (21 U.S.C. 360c(a)(3)) and 21 CFR 860.7(c)(2). (*See, e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (DC Cir. 1985); *Contact Lens Assoc.* v. *FDA,* 766 F.2d 592 (DC Cir.), cert. denied, 474 U.S. 1062 (1985)). FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).

In accordance with section 513(e) of the FD&C Act and 21 CFR 860.130(b)(1), based on new information with respect to the device, FDA, on its own initiative, is reclassifying this device from class III to class II.

II. Regulatory History of the Device

As discussed in the proposed rule, the agency issued a final rule classifying this device into class III (53 FR 23856, June 24, 1988). In August 1997, in response to FDA's order for the submission of information on the TOCE, two manufacturers submitted 515(i) summaries of safety and effectiveness information to the agency for the TOCE. FDA referred the 515(i) submissions to the General and Plastic Surgery Devices Panel (GPS Panel) for their recommendation on the requested reclassification. At a public meeting on November 17, 1998, the GPS Panel recommended that the device be retained in class III.

Since the 1998 GPS Panel meeting, three studies (two prospective and one retrospective) reported safe use and adequate healing of wounds using the TOCE. In addition, FDA has evaluated more than 20 years of clinical experience with the device and the agency's Medical Device Reports, and has found sufficient information to determine the risks to health associated with the use of this device and develop appropriate special controls.

As a result, in the **Federal Register** of April 6, 2006 (71 FR 17390), FDA proposed to reclassify the TOCE device from class III to class II. The device is intended to surround a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers such as bedsores. Elsewhere in the **Federal Register** of April 6, 2006 (71 FR 17476), FDA announced the availability of the draft guidance document entitled "Class II Special Controls Draft Guidance Document: Topical Oxygen Chamber for Extremities," which FDA intended to serve as the special control for this device type following the effective date of the final reclassification rule.

Interested persons were invited to comment until July 5, 2006, on the proposed regulation and special controls draft guidance document.

III. Analysis of Comments and FDA's Response

FDA received 11 comments on the proposed rule. The comments received discussed academic literature, clinical experiences, and patient outcomes that support the proposed reclassification's determinations of the safety and effectiveness of the TOCE device. The comments did not recommend any changes to the proposed regulation.

IV. Summary of Final Rule

Based on the information discussed in the preamble to the proposed rule, the comments on the proposed rule, a review of the Manufacturer and User Facility Device Experience (MAUDE) database, and a review of current scientific literature, FDA concludes that special controls, in conjunction with general controls, will provide reasonable assurance of the safety and effectiveness of TOCE. The agency is, therefore, reclassifying TOCE from class III (premarket approval) into class II (special controls) and issuing a final rule that revises 21 CFR 878.5650. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities," which will serve as the special control for this device. Following the effective date of this final classification rule, any firm

submitting a 510(k) premarket notification for a TOCE will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Section 510(m) of the FD&C Act (21 U.S.C. 360(m)) 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. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the TOCE and, therefore, this device type is not exempt from premarket notification requirements.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification 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.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule reclassifying this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs, and the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State law conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain State requirements "different from or in addition to" certain Federal requirements applicable to devices. (See section 521 of the FD&C Act (21 U.S.C. 360k); *Medtronic Inc.,* v. *Lohr,* 518 U.S. 470 (1996); *Riegel* v. *Medtronic Inc.,* 128 S. Ct. 999 (2008)). The special controls established by this final rule create "requirements" for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. See *Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–742 (9th Cir. 1997).

VIII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required. FDA concludes that the special controls guidance document identified by this rule contains information collection provisions that are subject to review and clearance by OMB under the PRA.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled, "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities." The notice contains an analysis of the paperwork burden for the guidance.

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 21 CFR part 878 continues to read as follows:

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

■ 2. Section 878.5650 is revised to read as follows:

§ 878.5650 Topical oxygen chamber for extremities.

(a) *Identification.* A topical oxygen chamber for extremities is a device that is intended to surround a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers such as bedsores.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance: Topical Oxygen Chamber for Extremities." See § 878.1(e) for the availability of this guidance document.

Dated: April 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9899 Filed 4–22–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2011–OS–0008]

32 CFR Part 321

Privacy Act of 1974; Implementation

AGENCY: Defense Security Service, DoD.

ACTION: Direct final rule with request for comments.

SUMMARY: The Defense Security Service is deleting an exemption rule for V5–05 entitled "Joint Personnel Adjudication System (JPAS)" in its entirety. The system has been transferred to the Office of the Secretary of Defense.

This direct final rule makes nonsubstantive changes to the Defense