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

Security Service Privacy Program rules. These changes will allow the Department to transfer this system to another organization within the Department. This will improve the efficiency and effectiveness of DoD's program by preserving the exempt status of the records when the purposes underlying the exemption are valid and necessary to protect the contents of the records.

This rule is being published as a direct final rule as the Department of Defense does not expect to receive any adverse comments, and so a proposed rule is unnecessary.

DATES: The rule will be effective on July 5, 2011 unless comments are received that would result in a contrary determination. Comments will be accepted on or before June 24, 2011.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, Room 3C843, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Leslie Blake at (703) 325–9450.

SUPPLEMENTARY INFORMATION:

Direct Final Rule and Significant Adverse Comments

DoD has determined this rulemaking meets the criteria for a direct final rule because it involves nonsubstantive changes dealing with DoD's management of its Privacy Progams. DoD expects no opposition to the changes and no significant adverse comments. However, if DoD receives a significant adverse comment, the Department will withdraw this direct final rule by publishing a notice in the **Federal Register**. A significant adverse comment is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, DoD will consider whether it warrants a substantive response in a notice and comment process.

Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"

It has been determined that Privacy Act rules for the Department of Defense are not significant rules. The rules do not (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in these Executive orders.

Public Law 96–354, "Regulatory Flexibility Act" (5 U.S.C. Chapter 6)

It has been determined that Privacy Act rules for the Department of Defense do not have significant economic impact on a substantial number of small entities because they are concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Public Law 96–511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

It has been determined that Privacy Act rules for the Department of Defense impose no additional information collection requirements on the public under the Paperwork Reduction Act of 1995.

Section 202, Public Law 104–4, "Unfunded Mandates Reform Act"

It has been determined that Privacy Act rulemaking for the Department of Defense does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more and that such rulemaking will not significantly or uniquely affect small governments.

Executive Order 13132, "Federalism"

It has been determined that Privacy Act rules for the Department of Defense do not have federalism implications. The rules do not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

List of Subjects in 32 CFR Part 321

Privacy.

Accordingly, 32 CFR 321 is amended as follows:

PART 321—DEFENSE SECURITY SERVICE PRIVACY PROGRAM

■ 1. The authority citation for 32 CFR part 321 continues to read as follows:

Authority: Pub. L. 93–579, 88 Stat. 1896 (5 U.S.C. 552a).

■ 2. In § 321.13, remove and reserve paragraph (h) to read as follows:

§ 321.13 Exemptions.

* * * * *

(h) [Reserved].

Dated: April 8, 2011.

Patricia Topping,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2011–9747 Filed 4–22–11; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2011–OS–0009]

32 CFR Part 323

Privacy Act of 1974; Implementation

AGENCY: Defense Logistics Agency, DoD.

ACTION: Direct final rule with request for comments.

SUMMARY: The Department of Defense is updating the Defense Logistics Agency Privacy Act Program Rules, by adding the exemption rules (j)(2), (k)(2), (k)(3), (k)(4), (k)(5), (k)(6), and (k)(7) for S510.30, Freedom of Information Act/Privacy Act Requests and Administrative Appeal Records to accurately describe the basis for exempting the records. The S510.30 system of records notice was printed on January 22, 2009 in the **Federal Register**.

This direct final rule makes nonsubstantive changes to the Defense Logistics Agency Privacy Program rules. These changes will allow the Department to exempt records from certain portions of the Privacy Act. This will improve the efficiency and effectiveness of DoD's program by preserving the exempt status of the