

FDC date	State	City	Airport	FDC No.	Subject
04/02/03 ...	IL	Decatur	Decatur	3/2578	LOC BC Rwy 24, Amdt 10
04/02/03 ...	IL	Decatur	Decatur	3/2581	ILS Rwy 6, Amdt 13A
04/02/03 ...	IL	Decatur	Decatur	3/2582	VOR Rwy 36, Amdt 15
04/02/03 ...	TX	San Antonio	San Antonio Intl	3/2595	ILS Rwy 12R (Cat I, II), Amdt 13
04/03/03 ...	OH	Cleveland	Cleveland-Hopkins Intl	3/2609	ILS Rwy 6L, Orig-B
04/04/03 ...	NY	Newburgh	Newburgh/Stewart Intl	3/2641	VOR Rwy 27, Amdt 4A
04/04/03 ...	PA	Franklin	Venango Regional	3/2654	ILS Rwy 20, Amdt 4B
04/07/03 ...	VT	Burlington	Burlington Intl	3/2624	ILS/DME Rwy 33, Orig-D
04/09/03 ...	SC	Myrtle Beach	Myrtle Beach Intl	3/2735	RADAR-1, Amdt 1
04/09/03 ...	SC	Myrtle Beach	Myrtle Beach Intl	3/2736	ILS Rwy 18, Amdt 1C
04/09/03 ...	SC	Myrtle Beach	Myrtle Beach Intl	3/2737	RNAV (GPS) Rwy 18, Amdt 1
04/09/03 ...	TN	Dickson	Dickson Muni	3/2754	VOR/DME Rwy 17, Amdt 4B
04/09/03 ...	TN	Dickson	Dickson Muni	03/2755	RNAV (GPS) Rwy 17, Orig
04/09/03 ...	TN	Dickson	Dickson Muni	3/2756	NDB Rwy 17, Amdt 2A

¹ Replaces 3/2370.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 02P-0494]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Optical Impression Systems for Computer Assisted Design and Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from the premarket notification requirements for data acquisition units for ceramic dental restoration systems. This rule exempts from premarket notification data acquisition units for ceramic dental restoration systems and establishes a guidance document as a special control for this device. FDA is publishing this order in accordance with the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This rule is effective April 22, 2003.

FOR FURTHER INFORMATION CONTACT: Kevin Mulry, Center for Devices and Radiological Health (HFZ-480), Food

and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283, ext 185.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, Class II, or Class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94-295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101-629)), devices are to be classified into Class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into Class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into Class III (premarket approval), if there is insufficient information to support classifying a device into Class I or Class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of

the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105-115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of Class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published

that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that 1 day after date of publication of the list under section 510(m)(1) of the act, FDA may exempt a device on its own initiative, or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a Class II device. These factors are discussed in the guidance that the agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff." That guidance can be obtained through the Internet on the CDRH home page at <http://www.fda.gov/cdrh.guidance.html> or by facsimile through CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111. Specify "159" when prompted for the document shelf number.

III. Petition

On October 25, 2002, FDA received a petition requesting an exemption from premarket notification for data acquisition units for ceramic dental restoration systems. These devices are currently classified under § 872.3660 *Impression material* (21 CFR 872.3660) as an accessory. In the **Federal Register** of January 30, 2003 (67 FR 2787), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by March 3, 2003. FDA did not receive any comments.

FDA has determined that maintaining classification of the data acquisition units in Class II and exempting them from the premarket notification requirements, with the guidance document as a special control, will provide reasonable assurance of the safety and effectiveness of these devices and, therefore, they meet the criteria for

exemption from the premarket notification requirements. For precision and clarity, FDA is: (1) Designating these devices as "optical impression systems for computer assisted design and manufacturing (CAD/CAM);" (2) placing them in new § 872.3661; (3) exempting them from the premarket notification requirements; and (4) establishing the guidance document entitled "Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA" as the special control for these devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this guidance document. Following the effective date of this final rule any firm submitting a 510(k) premarket notification for an optical impression system for CAD/CAM will need to address the issues covered in the special control 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. All other devices classified under § 872.3660 will continue to be classified in that section and subject to the same regulatory requirements as before.

For the benefit of the reader, FDA is also adding a § 872.1(e) to direct the reader to the Web site for guidance documents.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

V. 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 (Public Law 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 consistent with the regulatory philosophy and principles identified in the Executive

order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review 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. This rule will relieve a burden and simplify the marketing of these devices. The guidance document is based on existing review practices and will not impose any new burdens on these devices. The agency, therefore, certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 872

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 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

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

■ 2. Section 872.1 is amended by adding paragraph (e) to read as follows:

§ 872.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh.guidance.html>. ■ 3. Section 872.3660 is amended by revising paragraph (b) to read as follows:

§ 872.3660 Impression material.

* * * * *

(b) *Classification*. Class II (Special Controls).

■ 4. Section 872.3661 is added to subpart D to read as follows:

§ 872.3661 Optical Impression Systems for CAD/CAM.

(a) *Identification*. An optical impression system for computer assisted design and manufacturing (CAD/CAM) is a device used to record the topographical characteristics of teeth, dental impressions, or stone models by analog or digital methods for use in the computer-assisted design and manufacturing of dental restorative prosthetic devices. Such systems may consist of a camera, scanner, or equivalent type of sensor and a computer with software.

(b) *Classification*. Class II (Special Controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of the chapter subject to the limitations in § 872.9. The special control for these devices is the FDA guidance document entitled "Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA." For the availability of this guidance document, see § 872.1(e).

Dated: April 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-9869 Filed 4-21-03; 8:45 am]

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COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

28 CFR Part 810

[CSOSA-0002-F]

RIN 3225-AA00

Community Supervision: Administrative Sanctions

AGENCY: Court Services and Offender Supervision Agency for the District of Columbia.

ACTION: Final rule.

SUMMARY: The Court Services and Offender Supervision Agency for the District of Columbia ("CSOSA") is

finalizing its interim rule on administrative sanctions which may be imposed on offenders under CSOSA's supervision who violate the general or specific conditions of their release. The purpose of imposing sanctions is to enable CSOSA staff to respond as swiftly, certainly, and consistently as practicable to non-compliant behavior. Using sanctions will reduce the number of violation reports sent to the releasing authority (for example, the sentencing court or the United States Parole Commission). CSOSA staff will be able to refer offenders back to the releasing authority having demonstrated that CSOSA has exhausted the range of options at its disposal to change the offender's non-compliant behavior. The releasing authority may then concentrate on those referrals which fully merit scrutiny. The purpose of the regulations is to prevent crime, reduce recidivism, and support the fair administration of justice through the promotion of effective community supervision.

EFFECTIVE DATE: April 22, 2003.

ADDRESSES: Office of the General Counsel, CSOSA, Room 1253, 633 Indiana Avenue, NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Roy Nanovic, Records Manager (telephone: (202) 220-5359; e-mail: roy.nanovic@csosa.gov).

SUPPLEMENTARY INFORMATION: CSOSA is finalizing its interim regulations on administrative sanctions which may be imposed on offenders under CSOSA's supervision who violate the general or specific conditions of their release. These interim regulations were published in the **Federal Register** on September 20, 2001 (66 FR 48336).

CSOSA is responsible for the supervision of adults on probation, parole, or supervised release in the District of Columbia. A critical factor in such supervision is the ability to introduce an accountability structure into the supervision process and to provide swift, certain, and consistent responses to non-compliant behavior. Under traditional procedures, when offenders under CSOSA supervision violate the general or specific conditions of their release, CSOSA staff must refer the matter to the releasing authority. In most cases, the releasing authority is the sentencing court (usually the Superior Court of the District of Columbia) or the United States Parole Commission ("USPC"). The releasing authority, however, may include any of the jurisdictions participating in the Interstate Compact. The referrals

necessarily increase the workload for the releasing authority. The response and response time between a reported violation and a hearing is consequently uncertain.

Regulations issued by the USPC (see 28 CFR 2.85(a)(15)) authorize CSOSA's community supervision officers to impose graduated sanctions if a parolee has tested positive for illegal drugs or has committed any non-criminal violation of the conditions of parole. The USPC retains the authority to override an imposed sanction and issue a warrant or summons if it finds that the parolee is a risk to public safety or is not complying in good faith with the sanction. The Superior Court of the District of Columbia typically includes authorization for a program of graduated sanctions in connection with illicit drug use or other violation of conditions of probation as part of the offender's general conditions of probation. By issuing these interim regulations on the imposition of administrative sanctions, CSOSA intended to ensure the consistency, certainty, and timeliness of imposed sanctions for all offenders (parolees, probationers, and supervised releasees) under its supervision.

Under these interim regulations, CSOSA established a supervision level and minimum contact requirements for the individual offender (see § 810.1). CSOSA uses an accountability contract (see § 810.2) between the offender and CSOSA to define non-compliant behavior. The accountability contract outlines the expectations for behavior and the consequences (that is, the sanctions) for failing to comply. The sanctions present the community supervision officer with a range of corrective actions (see § 810.3) which can be applied short of court or USPC approval. The goal of these sanctions is to change offender behavior. Imposing the sanctions quickly and consistently may prevent escalation of the offender's non-compliant behavior.

The accountability contract identifies a schedule for imposing sanctions which is keyed to the recurrence of violations. The accountability contract also provides for positive reinforcements for compliant behavior (see § 810.3(d)).

Administrative sanctions accordingly are a component of effective supervision. When CSOSA does make a referral to the court or to the USPC, it will be able to demonstrate that it has exhausted the range of options at its disposal with respect to the offender's non-compliant behavior or that the violation is so severe immediate action by the releasing authority may be