

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

<sup>1</sup> 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