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Display Date 12-9-04
Publication Date 12-10-04
Certifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 2004N–0477]

Medical Devices; General Hospital and Personal Use Devices; Classification of Implantable Radiofrequency Transponder System for Patient Identification and Health Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the implantable radiofrequency transponder system for patient identification and health information into class II (special controls). The special control that will apply to the device is the guidance document entitled "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information." The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule is effective [*insert date 30 days after date of publication in the* **Federal Register**]. The classification was effective October 12, 2004.

FOR FURTHER INFORMATION CONTACT: Gail Gantt, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

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SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or 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 act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request that FDA classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a document in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued a document on July 22, 2004, classifying the VERICHIP Health Information Microtransponder System in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On August 4, 2004, Digital Angel Corp. submitted a petition requesting classification of the VERICHIP Health Information Microtransponder System under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified 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 to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the VERICHIP Health Information Microtransponder System can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name implantable radiofrequency transponder system for patient identification and health information and is identified as a system intended to enable access to secure patient identification and corresponding health information. This system may include a passive

implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code that is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.

The potential risks to health associated with the device are adverse tissue reaction, migration of implanted transponder, compromised information security, failure of implanted transponder, failure of inserter, failure of electronic scanner, electromagnetic interference, electrical hazards, magnetic resonance imaging incompatibility, and needle stick. The special controls document aids in mitigating the risks by identifying performance and safety testing, and appropriate labeling.

Therefore, in addition to the general controls of the act, an implantable radiofrequency transponder system for patient identification and health information is subject to special controls identified as the guidance document entitled "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information."

FDA believes that following the class II special controls guidance document generally addresses the risks to health identified in the previous paragraph. Therefore, on October 12, 2004, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding 21 CFR 880.6300.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the 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 not necessary to provide reasonable assurance of the safety and effectiveness of the implantable radiofrequency transponder system for patient identification and health information because the manufacturing controls, software validation science, and electrical safety standards in the special control guidance are well known. The measures needed to keep patient data secure are commonly in use. Thus, persons who intend to market this device type need not submit to FDA a premarket notification submission containing information on an implantable radiofrequency transponder system for patient identification and health information, unless they exceed the limitations on exemptions in 21 CFR 880.9 (e.g., different intended use or fundamental scientific technology).

For the convenience of the reader, FDA is also adding new 21 CFR 880.1 to inform readers of the availability of guidance documents referenced in 21 CFR part 880.

II. 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, 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 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 classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant 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 $110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. 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 Executive

order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

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.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Digital Angel Corp., dated August 4, 2004.

List of Subjects in 21 CFR Part 880

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 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for 21 CFR part 880 continues to read as follows:

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

per K. Thornton, OFR 12-7-04 AR

■ 2. Section 880.1 is ~~revised~~ amended by adding new paragraph (e) to read as follows:

§ 880.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/cdrh/guidance.html.*

■ 3. Section 880.6300 is added to subpart G to read as follows:

§ 880.6300 Implantable radiofrequency transponder system for patient identification and health information.

(a) *Identification.* An implantable radiofrequency transponder system for patient identification and health information is a device intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code that is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information." See § 880.1(e) for the availability of this guidance

document. This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

Dated: 11/30/04
November 30, 2004.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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