PART 171—FINES, PENALTIES, AND FORFEITURES

■ 2. The authority citation for part 171, CBP Regulations, continues to read as follows:

Authority: 18 U.S.C. 983; 19 U.S.C. 66, 1592, 1593a, 1618, 1624; 22 U.S.C. 401; 31 U.S.C. 5321; 46 U.S.C. App. A. 320.

Subpart F also issued under 19 U.S.C. 1595a, 1605, 1614.

* * * * *

§ 171.62 [Amended]

■ 3. Section 171.62 is amended by removing paragraphs (c) and (d).

§ 171.63 [Removed and reserved]

■ 4. Section 171.63 is removed and reserved.

Dated: October 12, 2007.

W. Ralph Basham,

Commissioner, U.S. Customs and Border Protection.

[FR Doc. E7–20471 Filed 10–18–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 2007N–0328]

Medical Devices; General Hospital and Personal Use Devices; Classification of Remote Medication Management System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the remote medication management systems into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled, ''Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System,'' which will serve as the special control for this device type. The agency is classifying this device type into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of these devices.

DATES: This final rule is effective November 19, 2007. The classification was effective June 13, 2007.

FOR FURTHER INFORMATION CONTACT: Richard Chapman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2585.

SUPPLEMENTARY INFORMATION:

I. What is the Background of This Rulemaking?

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 the device is classified or reclassified into class I or class 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 predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (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 FDA to 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 type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice 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 an order on September 20, 2006, classifying the INRange Remote Medication Management 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 that was subsequently reclassified into class I or class II. On September 25, 2006, INRange Systems, Inc., submitted a petition requesting classification of the INRange Remote Medication Management 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 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 remote medication management systems can be classified into class II with the establishment of special controls. FDA believes that these special controls, in addition to general controls, are adequate to provide reasonable assurance of the safety and effectiveness of the device. The device is assigned the generic name ''Remote Medication Management System.'' A remote medication management system is a device composed of clinical and communications software, a medication delivery unit, and medication packaging. The system is intended to store the patient's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient's prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and to record a history of the event for the health care professional. The system is intended for use as an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic.

FDA has identified the following risks to health associated with this type of device:

- Improper dosage delivered to patient,
- Cross-contamination of medications—unintended drug interactions,
- Compromised information security,
- Failure of the device—inability to deliver medication,
- Electromagnetic interference—electromagnetic emissions interfering with other medical devices or electromagnetic susceptibility causing the device to function improperly due to emissions of other devices, and
- Electrical and mechanical hazards—electrical shock, pinching.

FDA believes that the class II special controls guidance document will aid in mitigating the potential risks to health as described in table 1 of this document.

TABLE 1.—RISKS TO HEALTH AND MITIGATION MEASURES

Identified Risk	Recommended Mitigation Measures
Improper dosage delivered to patient	Software validation Simulated use testing Labeling
Cross-contamination of medications	Simulated use testing
Compromised information security	Software validation Simulated use testing
Failure of the device	Software validation Simulated use testing Labeling
Electromagnetic interference	Electromagnetic compatibility Labeling
Electrical and mechanical hazards	Electrical and mechanical safety testing Labeling

FDA believes that the special controls, in addition to general controls, address the risks to health identified previously and provide reasonable assurances of the safety and effectiveness of the device type. Thus, on June 13, 2007, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification at 21 CFR 880.6315.

Following the effective date of the final classification rule, manufacturers will need to address the issues covered in the special controls guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirement 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. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the remote medication management system they intend to market.

II. What is the Environmental Impact of This Rule?

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. Thus, neither an environmental assessment nor an environmental impact statement is required.

III. What is the Economic Impact of This Rule?

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 as defined by 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 this device into class II will relieve manufacturers 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 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 $127 million, using the most current (2006) 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.

IV. Does This Final Rule Have Federalism Implications?

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. How Does This Rule Comply With the 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 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the guidance for the final rule. This guidance, ''Class II Special Controls Guidance Document: Remote Medication Management System,'' references previously approved collections of information found in FDA regulations.

VI. What References Are on Display?

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 INRange Systems, Inc., dated September 25, 2006.

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.

■ 2. Section 880.6315 is added to subpart G to read as follows:

§ 880.6315 Remote Medication Management System.

(a) *Identification.* A remote medication management system is a device composed of clinical and communications software, a medication delivery unit, and medication packaging. The system is intended to store the patient's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient's prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and to record a history of the event for the health care professional. The system is intended for use as an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic.

(b) *Classification.* Class II (special controls). The special control is: The FDA guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System.'' See § 880.1(e) for availability of this guidance document.

Dated: October 3, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–20633 Filed 10–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 203

RIN 1510–AB01

Payment of Federal Taxes and the Treasury Tax and Loan Program

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Interim final rule.

SUMMARY: As part of an ongoing effort to review and streamline its regulations, the Financial Management Service (FMS) has revised its regulation governing the Treasury Tax and Loan (TT&L) program. The changes update the rule to reflect the reorganization and enhancement of the TT&L program, including changes in terminology, and simplify the rule by deleting procedures and provisions that appear in other regulations or in the Treasury Financial Manual. FMS also has rewritten this regulation in plain language, thus making it clearer and easier to understand.

DATES: This interim final rule is effective October 19, 2007. Comments must be received by December 18, 2007.

ADDRESSES: The Financial Management Service began participating in the U.S. government's eRulemaking Initiative by publishing rulemaking information on *www.regulations.gov*. Regulations.gov offers the public the ability to comment on, search, and view publicly available rulemaking materials, including comments received on rules.

Comments on this rule, identified by docket FISCAL–FMS–2007–0007, should only be submitted using the following methods:

- *Federal eRulemaking Portal: www.regulations.gov*. Follow the instructions on the Web site for submitting comments.
- *Mail:* Thompson Sawyer, Director, Investment Management Division, Financial Management Service, 401 14th Street, SW., Washington, DC 20227.

The fax and e-mail methods of submitting comments on rules to FMS have been retired.

Instructions: All submissions received must include the agency name (''Financial Management Service'') and docket number FISCAL–FMS–2007–0007 for this rulemaking. In general, comments will be published on Regulations.gov without change, including any business or personal information provided. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may also inspect and copy this proposed rule at: Treasury Department Library, Freedom of Information Act (FOIA) Collection, Room 1428, Main Treasury Building, 1500 Pennsylvania Avenue, NW., Washington, DC 20220. Before visiting, you must call (202) 622–0990 for an appointment.

FOR FURTHER INFORMATION CONTACT: Thompson Sawyer, Director, Investment Management Division, at (202) 874–7150 or *thompson.sawyer@fms.treas.gov* or Ellen M. Neubauer, Senior Attorney, at (202) 874–6680 or *ellen.neubauer@fms.treas.gov.*

SUPPLEMENTARY INFORMATION:

1. Background

The Treasury Tax and Loan (TT&L) program encompasses two separate components: A depositary component through which we collect Federal tax deposits and payments from business taxpayers for employee withholding and other types of taxes, and an investment component through which we invest short-term operating balances not needed for immediate cash outlays. Examples of the investment component are retention of tax deposits, direct investments, term investments or other investment programs. Approximately 950 TT&L depositaries borrow excess short-term Treasury operating funds by participating in the investment component of the TT&L program. Through agreements executed pursuant to Part 203, participating depositaries borrow Treasury funds in the form of a note secured with collateral pledged to