Autopilot ..... Disengage.
Power Levers ..... As required.
Elevator Trim Wheels ..... As required.

CAUTION: MANUALLY SET THE ELEVATOR TRIM WHEELS TO THE REQUIRED DESCENT ATTITUDE.

If any trim system binding (if trim wheel rotates more than one trim wheel index mark after being released), or abnormal trim operation is observed:

Elevator Trim Jamming Procedure ..... Perform.

CAUTION: DO NOT TRY TO RE-ENGAGE THE AUTOPILOT.

If no abnormal trim operation is observed:

Flight Director Vertical Mode ..... As required.
Autopilot ..... Reengage.

''(2) If an elevator trim jamming is detected during flight and the pitch trim system resumes normal operation on ground, only a ferry flight using a special permit may be performed to return the aircraft to a maintenance base for replacement of the actuators. In this case, the use of autopilot is prohibited.''

Placard Installation

(c) Within 300 flight hours after the effective date of this AD, install two placards on the glareshield, advising the flight crew to check the pitch trim before initial descent, in accordance with Part II of the Accomplishment Instructions of EMBRAER Service Bulletin 120–25–0262, Change 02, dated October 30, 2003.

Elevator Trim System Modification

(d) Within 36 months after the effective date of this AD, modify the elevator trim system, in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 120–27–0095 and 120–27–0096, both dated February 16, 2007. Accomplishment of the modification terminates the requirements of paragraphs (a), (b), and (c) of this AD, and the corresponding AFM revisions and placards may be removed.

Parts Installation

(e) As of 36 months after the effective date of this AD, no person may install, on any airplane, an elevator trim tab actuator or control cable having a part number identified in Table 1 of this AD.

TABLE 1.—PROHIBITED PARTS

Part	Part No.
Elevator trim tab actuator ..	120–19685–001 120–19685–003 120–19685–007 120–38650–001 120–39205–001 5299 5299–1
Control cable	120–27729–095 120–27729–097 120–31370–095 120–31370–097

Alternative Methods of Compliance

(f)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Note 1: The subject of this AD is addressed in Brazilian airworthiness directive 2001–06–01R4, effective August 23, 2007.

Issued in Renton, Washington, on February 1, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–2356 Filed 2–7–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 2007N–0484]

Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify, on its own initiative, the Medical Device Data System (MDDS) from class III (premarket approval) to class I (general controls). This action does not include medical device data systems with new diagnostic or alarm functions. FDA is also proposing that the MDDS be exempt from the premarket notification requirements when it is indicated for use only by a healthcare professional and does not perform irreversible data compression.

DATES: Submit written or electronic comments on the proposed rule by May 8, 2008. Submit comments regarding information collection by March 10, 2008, to the Office of Management and Budget (OMB) (see **ADDRESSES**). FDA proposes that any final regulation based on this proposal become effective 60 days after its date of publication in the **Federal Register**. See section VIII of the **SUPPLEMENTARY INFORMATION** section of the preamble for further information about the effective date.

ADDRESSES: You may submit comments, identified by Docket No. 2007N–0484, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the followings ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No.(s) and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the

''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Information Collection Provisions: Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Anthony D. Watson, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513(a)(1) of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are:

- Class I (general controls),
- Class II (special controls), and
- Class III (premarket approval).

FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as ''preamendment devices.'' FDA classifies these devices after it:

1. Receives a recommendation from a device classification panel (an FDA advisory committee);
2. Publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and
3. Publishes a final regulation classifying the device.

FDA has classified most preamendments devices under these procedures.

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 of the regulations (21 CFR part 807).

Reclassification of postamendment devices is governed by section 513(f)(3) of the act, formerly section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services for the issuance of an order classifying the device in class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new classification have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

FDAMA added section 510(l) to the act. Section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. FDA refers to the criteria that designate a class I device as not exempt from premarket notification as ''reserved criteria.'' An exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.

II. Regulatory History of the Device

Computer-based and software-based products are subject to regulation as devices when they meet the definition of a device contained in section 201(h) of the act (21 U.S.C. 321(h)). In 1989, FDA prepared a general policy statement on how it planned to determine whether a computer-based product and/or software based product is a device and, if so, how FDA intended to regulate it. This document became known as the ''Draft Software Policy.'' The scope and intention of the 1989 policy were based on the existing state of computer and software technology at that time. That policy included the principle that the level of FDA oversight of software should depend primarily on the risk to the patient should the software fail to perform in accordance with its specifications.

Since 1989, the use of computer-based products and software-based products as medical devices has grown exponentially. In addition, device interconnectivity and complexity have grown in ways that could not have been predicted in 1989. This growth and expansion have created new considerations for elements of risk that did not previously exist. FDA realized that the Draft Software Policy was not adequate to address all of the issues related to the regulation of computer-based and software-based medical devices. Based on this history and the complexity and diversity of computer software, FDA decided it would be impractical to prepare one ''software'' or ''computer'' policy that would be able to address all the issues related to the regulation of computer- and software-based medical devices. Nonetheless, the principle that the level of FDA oversight of software should depend primarily on the risk to the patient should the software fail to perform in accordance with its specifications remains important. Many software classifications reflect this principle, including:

- FDA has classified software used in computer aided detection of cancerous lesions in the breast in class III;
- FDA has classified software used in computer tomography (CT) and X-ray systems to provide images to assist in clinical decisionmaking in class II; and
- FDA has classified laboratory information systems in class I.

This principle also informs this proposed reclassification, in which FDA is focusing on a category of post amendment computer- and software-based devices that present a low risk and should not be subject to premarket review that have not been classified elsewhere. An examination of modern medical device networks and computer infrastructure helped FDA to identify a category of computer based and software products that meet the definition of a device, which the FDA would consider to pose minimal risks, and that should not be Class III and should not require premarket submission. This medical device has been named a ''Medical Device Data System.''

III. Device Description

A medical device data system (MDDS) is a device intended to provide one or more of the following uses:

- The electronic transfer or exchange of medical device data from a medical device, without altering the function or parameters of any connected devices. For example, this would include software that interrogates a ventilator every 15 minutes and transfers information about patient CO^2 levels to a central patient data repository;

• The electronic storage and retrieval of medical device data, without altering the function or parameters of connected devices. For example, this would include software that stores historical blood pressure information for later review by a healthcare provider;

• The electronic display of medical device data, without altering the function or parameters of connected devices. For example, this would include software that displays the previously stored electrocardiogram for a particular patient;

• The electronic conversion of medical device data from one format to another format in accordance with a preset specification. For example, this would include software that converts digital data generated by a pulse oximeter into a digital format that can be printed.

• Examples of medical device data systems that would be used in the home are systems that periodically collect data from glucose meters or blood pressure devices for later review by a healthcare provider.

Medical device data consist of numerical or other information available from a medical device in a form suitable for processing by computer. Medical device data can represent many types of information (e.g., clinical values, alarm conditions, error messages). MDDS are not intended or designed to provide any real time, active, or online patient monitoring functions. Medical device data systems can deliver and store alarm data but do not have the capability to display, create, or detect alarm conditions, or to actually sound an alarm. In particular, a MDDS can record the fact that an alarm sounded, but cannot by itself sound an alarm in response to patient information. Medical device data systems cannot create alarms that are not already present from the connected medical devices. By themselves, MDDS do not provide any diagnostic or clinical decision making functions. Medical device data systems can transmit, exchange, store, or retrieve data in its original format or can be used to convert the medical device data from one format to another so that the arrangement or organization of the medical device data is in accordance with preset specifications.

In developing its current regulatory strategy for MDDS, FDA considered how the risks presented by an MDDS compare to existing manual processes for managing these data. Hospitals, clinics, and other healthcare facilities are well-aware of the shortcomings of manual functions and have introduced other manual oversight to reduce their effects, such as audits of records and multiple-person checks of paperwork prior to treatments. These facilities have also introduced electronic systems to help reduce the human element in these errors. However, when data are being stored, retrieved, transferred, exchanged, or displayed electronically, an additional element of risk is introduced. This element of risk would not be present for a manual transfer of files or information because the information is readily apparent to the healthcare provider.

When manual data is converted to electronic form, data can be altered in such a way as to not be transparent to the user and pose a risk to the patient. In effect, even though manual functions have their risks (e.g., illegible handwriting, wrong charts, etc.), when these functions are automated, users tend to rely entirely on the technology because the technology is assumed to alleviate those risks. This is especially true when software systems are designed to interface with a number of unspecified medical devices. Thus, regulatory oversight of MDDS is critical to ensuring that there is an adequate expectation of performance.

It is FDA's long-standing practice to not regulate those manual office functions that are simply automated for the ease of the user (e.g., office automation) and that do not include MDDS as described previously. For example, the report-writing functions of a computer system that allow for the manual (typewriter like) input of data by practitioners would not be considered as a MDDS, because these systems are not directly connected to a medical device. In addition, software that merely performs library functions, such as storing, indexing, and retrieving information not specific to an individual patient, is not considered to be a medical device. Examples include medical texts or the Physician's Desk Reference on CD-ROM that are indexed and cross-referenced for ease of use. This proposed regulation does not address software that allows a doctor to enter or store a patient's health history in a computer file.

IV. Proposed Reclassification

Because MDDS that are subject to the rulemaking are new post amendment devices, they are deemed to be class III by operation of the statute (section 513(f) of the act (21 U.S.C. 360c(f)). FDA believes that classification in class I, with appropriate application of the Quality System Regulation (part 820 (21 CFR part 820)), will provide reasonable assurance of the safety and effectiveness of this device. FDA is proposing that the Medical Device Data System be reclassified from class III to class I. In addition, FDA is proposing that when the device is indicated for use only by a healthcare professional and does not perform irreversible data compression, in accordance with section 510(l) of the act (21 U.S.C. 360(l)), it would be exempt from the premarket notification procedures in subpart E of part 807, subject to the limitations in § 880.9 (21 CFR 880.9). For purposes of this regulation, ''healthcare professional'' is any practitioner licensed by the law of the State in which he or she practices to use or order the use of the device. When the device is indicated for use by a lay user, or performs irreversible data compression, FDA believes that the device presents a potential for unreasonable risk of illness or injury. FDA is proposing that MDDS devices indicated for lay use or that perform irreversible data compression not be exempt from premarket notification requirements.

V. Risks to Health

FDA believes that general controls, including the Quality System regulation and the requirements for Design Controls as per § 820.30, will provide a reasonable assurance of safety and effectiveness for a MDDS. Risks to health from this device would be caused by inadequate software quality. Specifically, the risk to health would be that incorrect medical device data is stored, retrieved, transferred, exchanged, or displayed, resulting in incorrect treatment or diagnosis of the patient. As explained below, FDA believes the risk related to inadequate software quality can be mitigated through application of the Quality System Regulation.

VI. Summary of Reasons for Reclassification

FDA believes that the MDDS should be reclassified into class I because general controls would provide reasonable assurance of safety and effectiveness and special controls and premarket approval are not necessary to provide such assurance. FDA believes that the application of the Quality System Regulation (part 820), particularly the design control provisions, would significantly reduce the risk of errors from these devices that might cause incorrect treatment or diagnosis of the patient. The design controls section (§ 820.30) of the QS regulation (§ 820.30) applies to the design of devices including class I devices with software. FDA does not intend to apply design controls retroactively to currently legally

marketed MDDS devices. However, changes to existing designs or to currently marketed devices must be made in accordance with design control requirements, even if the original design was not subject to these requirements, § 820.30. This approach to implementing design controls for MDDS is consistent with the way FDA implemented design controls after the issuance of the Quality System Regulation in 1996.

VII. Summary of Data Upon Which the Reclassification is Based

FDA is basing this proposed rule upon the history of use of this type of device in clinical practice as well as the substantial knowledge of FDA staff about this device type. These types of systems provide no new or unique clinical algorithms or clinical functions that have not already been reviewed and cleared in existing medical devices; therefore, no new pre-market review or evaluation should be required. Further, FDA believes that the proper application of a Quality System approach to the design and development of MDDS devices will ensure their quality. FDA believes that this is the least burdensome approach to the regulation of these medical devices.

VIII. Effective Date

FDA intends that this rule, if finalized, will become effective 60 days after the date of publication of the final rule. However, FDA intends to continue to exercise enforcement discretion after publication of any final rule so that manufacturers who are already on the market with MDDS devices may have sufficient time to come into compliance as follows: FDA expects manufacturers who are already marketing a MDDS device before publication of a final rule and who meet the criteria for exemption from premarket notification to register and list under part 807 within 60 days after publication of the final rule. If a premarket notification is required, FDA expects manufacturers who are marketing an MDDS device without FDA clearance to submit a premarket notification within 90 days of the effective date of a final rule and to obtain final clearance of a premarket notification within 180 days after publication of a final rule. FDA expects manufacturers who are required to obtain clearance of a premarket notification to register and list within 30 days after receiving a substantial equivalence order for their device. Manufacturers who are not already marketing an MDDS device will be required to comply with any final rule as of the effective date.

IX. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed 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.

X. Analysis of Impact

FDA has examined the impacts of the proposed 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 proposed 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 this action is deregulatory and imposes no new burdens, the agency certifies that the proposed 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 proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

Background

An MDDS is a device that electronically stores, transfers, displays, or reformats patient medical data. It does not provide any diagnostic or clinical decision making functions. A MDDS could, for example, store alarm data being generated by a connected medical device, but would not be able to generate alarms on its own. The MDDS device is currently classified into class III, the highest level of regulatory oversight. The MDDS was initially placed in this classification by default. MDDS manufacturers, as makers of class III devices, bear all costs associated with premarket approval, including the cost of submitting the premarket approval application (PMA) and payment of user fees. The costs associated with the submission of the PMA are substantial, potentially reaching $1,000.000.

Although we can identify several MDDS devices and device manufacturers, we nevertheless do not know the size of the affected industry because FDA has not been enforcing registration and listing requirements for manufacturers of MDDS devices. We welcome comment on the size and other characteristics of the affected industry.

FDA is proposing to reclassify MDDS devices from class III to class I. Based on the history of use of this type of device in clinical practice and on the experience of FDA reviewers, the agency concludes that in the hands of a healthcare professional, a MDDS is safe and effective under general controls. The application of general controls, including the software design controls in part 820, would be consistent with the principle of applying the least degree of regulatory control necessary to provide reasonable assurance of safety and effectiveness. The application of this lowest level of regulatory oversight would be consistent with the treatment of other devices with similar risk profiles. Software used to store, transmit, and communicate patient medical data, such as Laboratory Information Systems and Medical Image Communication Systems, is typically classified into class I.

FDA has already recognized that the class III requirements are not necessary for ensuring the safety and effectiveness of MDDS devices and has been exercising enforcement discretion with MDDS device manufacturers. These firms have not been required to submit PMAs or meet other requirements typically required of manufacturers of class III devices, but the agency believes that all or nearly all firms in this industry have in place good business practices, including quality systems. If FDA were to discontinue enforcement discretion, most firms would continue to comply with the class I provisions.

Cost of the Proposed Regulation

This proposed regulation is deregulatory. Device manufacturers currently subject to class III requirements would be subject to the

less burdensome requirements for makers of class I devices. Of course, changing the device classification may not have an impact on the practices of MDDS device manufacturers as long as FDA continues its practice of enforcement discretion. For the purpose of this analysis, however, we assume that enforcement discretion would not be permanent. The regulatory alternatives are therefore class III, II, or I controls, enforced by the agency. This proposed rule would re-classify MDDS devices as class I, which would reduce the applicable regulatory requirements.

Manufacturers of class I devices are required to: (1) Register and list their MDDS devices with the agency, (2) conform to applicable medical device current good manufacturing practice requirements (part 820), (3) comply with Medical Device Reporting (MDR) requirements (21 CFR part 803), and (4) submit a premarket notification for the device unless it is exempt. This proposed rule proposes to exempt MDDS devices unless they are indicated for use by someone other than a healthcare professional, perform irreversible data compression, or exceed the limitations in § 880.9. MDDS devices indicated for use solely by a healthcare professional, are exempt from the premarket notification requirements.

Registration and listing. The majority of manufacturers of MDDS devices would incur a cost to register and list their devices with the agency. We estimate this burden to be less than 1 hour per year for manufacturers familiar with this requirement, and up to 2 hours of time for manufacturers not currently producing any FDA-regulated devices. Manufacturers would also face user fees of $1,708 in fiscal year (FY) 2008 to register and list their devices with the agency. These fees would rise to $2,364 in 2012.

Current Good Manufacturing Practices (CGMP)/Quality System Regulation (QSR) compliance/Medical Device Reporting. Based on experience with this and similar devices, FDA believes that most manufacturers of these devices already have quality systems in place as part of good business practices. Good quality systems would include complaint-handling procedures. FDA's QSR (part 820) requirements are very flexible and FDA believes that these manufacturers will be able to conform their systems to FDA requirements with little difficulty or cost. Manufacturers are already required to report to FDA whenever they learn that their device may have caused or contributed to a death or serious injury to a patient. The cost of complying with these requirements would be small, but would vary depending on the number and nature of the devices manufactured and the nature of the firm's current quality system. Firms with existing quality systems should be able to adapt their complaint procedures to incorporate MDR reporting with little difficulty. Based on our understanding of the industry and that it has in place measures to ensure quality, we believe most firms would be able to adapt their systems to meet FDA's QSR and MDR regulations for no more than $20,000. Again, this would not be a cost imposed by this proposed rule, but the cost of an existing burden manufacturers may not have incurred because FDA's practice of enforcement discretion with manufacturers of MDDS devices.

Premarket notification. If FDA finalizes the classification of MDDS devices into class I, a manufacturer of a MDDS device that is indicated for use solely in a health care facility would not need to comply with the PMA requirement that applies to class III devices or submit a premarket notification. FDA is unaware of any MDDS devices that are not intended for use solely by healthcare professionals, so we believe all or nearly all MDDS devices will be exempt from premarket review. A manufacturer of a MDDS device that is indicated for use by anyone other than a healthcare professional or that performs irreversible data compression would need to submit a premarket notification, but the burden of submitting a premarket notification is substantially less than that of submitting a PMA. A premarket notification for a MDDS device would be far less complex than a PMA. The cost of preparing and submitting such a notification would be several thousand dollars. The user fees for a premarket notification would be $3,404 for FY 2008, increasing to $4,717 in 2012. In contrast, the cost of submitting a PMA can reach $1,000,000, plus user fees of an additional $185,000 in FY 2008, increasing to $256,384 in 2012.

In summary, this device reclassification would substantially reduce an existing burden on the manufacturers of MDDS devices. The regulatory burden of compliance with the general controls provisions applicable to the manufacturers of all class I devices is attributable to statutory requirements that already apply but have not been enforced. Assuming that continued enforcement discretion is not a viable long-term regulatory alternative, the proposed rule would reduce the regulatory burden for manufacturers of MDDS devices. Considering the cost of submitting a PMA plus the relevant user fees, the reduction could be $1,000,000 per device.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of the affected devices from class III to class I would relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), the agency does not believe that this proposed rule would have a significant economic impact on a substantial number of small entities. FDA requests comment on this issue.

XI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the proposed rule have been approved by OMB in accordance with the PRA under the QSR (part 820, OMB Control No. 0910–0073) and the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB Control No. 0910–0120).

XII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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 tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

XIII. Submission of Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

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, FDA proposes to amend 21 CFR part 880 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. Part 880 is amended in subpart G by adding § 880.6310 to read as follows:

§ 880.6310 Medical Device Data System.

(a) *Identification.* (1) A medical device data system (MDDS) is a device intended to provide one or more of the following uses:

(i) The electronic transfer or exchange of medical device data from a medical device, without altering the function or parameters of any connected devices.

(ii) The electronic storage and retrieval of medical device data from a medical device, without altering the function or parameters of connected devices.

(iii) The electronic display of medical device data from a medical device, without altering the function or parameters of connected devices.

(iv) The electronic conversion of medical device data from one format to another format in accordance with a preset specification.

(2) Medical device data consists of numerical or other information available from a medical device in a form suitable for processing by computer. Medical device data can represent any type of information or knowledge, e.g., clinical values, alarm conditions, error messages. This identification does not include a device that creates diagnostic, decision support, or alarm functions. It also does not include the report-writing functions of a data system that allows for the manual input of data by practitioners. This identification does not include devices with any real time, active, or online patient monitoring.

(b) *Classification.* Class I (general controls). When the device is indicated for use only by a healthcare professional and does not perform irreversible data compression, it is exempt from the premarket notification procedures in subpart E of part 807, subject to the limitations in § 880.9. When the device is indicated to be prescribed by a healthcare professional for use by a lay user, or performs irreversible data compression, or for over-the-counter use by a lay user, the device requires the submission and clearance of a premarket notification.

Dated: January 25, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–2325 Filed 2–7–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–153589–06]

RIN 1545–BG34

Time and Manner for Electing Capital Asset Treatment for Certain Self-Created Musical Works

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulation.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing a temporary regulation that provides the time and manner for making an election to treat the sale or exchange of musical compositions or copyrights in musical works created by the taxpayer (or received by the taxpayer from the works' creator in a transferred basis transaction) as the sale or exchange of a capital asset. The temporary regulation reflects changes to the law made by the Tax Increase Prevention and Reconciliation Act of 2005 and the Tax Relief and Health Care Act of 2006. The temporary regulation affects taxpayers making the election under section 1221(b)(3) of the Internal Revenue Code (Code) to treat gain or loss from such a sale or exchange as capital gain or loss. The text of the temporary regulation also serves as the text of this proposed regulation.

DATES: Written or electronic comments and requests for a public hearing must be received by May 8, 2008.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–153589–06), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–153589–06), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at www.regulations.gov (IRS REG–153589–06).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulation, Jamie Kim, (202) 622–4950; concerning submission of comments or requesting a hearing, *Richard.A.Hurst@irscounsel.treas.gov,* (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulation in the Rules and Regulations section of this issue of the **Federal Register** amends the Income Tax Regulations (26 CFR part 1) relating to section 1221(b)(3) of the Internal Revenue Code (Code). The temporary regulation provides rules regarding the time and manner for making an election under section 1221(b)(3) to treat the sale or exchange of certain musical compositions or copyrights in musical works as the sale or exchange of a capital asset. The text of the temporary regulation also serves as the text of this proposed regulation. The preamble to the temporary regulation explains the amendments.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before this proposed regulation is adopted as a final regulation, consideration will be given to any