(3) Sections 202(c), 210, 211, 212, 213, 214, 220, 221 and 222;

(4) Sections 305(c); and

(5) Any necessary enforcement provision of part III of the Federal Power Act (including but not limited to sections 306, 307, 308, 309, 314, 315, 316 and 316A) with regard to the sections listed in paragraphs (c)(1), (2), (3) and (4) of this section.

■ 9. In § 292.602, paragraphs (b) and (c) are revised to read as follows:

§ 292.602 Exemption of qualifying facilities from certain State law and regulation.

* * * * *

(b) *Exemption from the Public Utility Holding Company Act of 2005.* A qualifying facility described in paragraph (a) of this section or a utility geothermal small power production facility shall not be considered to be an ''electric utility company'' as defined in section 1262(5) of the Public Utility Holding Company Act of 2005, 42 U.S.C. 16451(5).

(c) *Exemption from certain State laws and regulations.*

(1) Any qualifying facility shall be exempted (except as provided in paragraph (b)(2)) of this section from State laws or regulations respecting:

(i) The rates of electric utilities; and

(ii) The financial and organizational regulation of electric utilities.

(2) A qualifying facility may not be exempted from State laws and regulations implementing subpart C.

(3) Upon request of a state regulatory authority or nonregulated electric utility, the Commission may consider a limitation on the exemptions specified in paragraph (b)(1) of this section.

(4) Upon request of any person, the Commission may determine whether a qualifying facility is exempt from a particular State law or regulation.

Note: The following Appendix will not be published in the Code of Federal Regulations.

Appendix: List of Petitioners Requesting Clarification or Submitting Comments

American Chemistry Council
American Electric Power Service Corporation jointly with AEP Texas North Company, AEP Texas Central Company, Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Public Service Company of Oklahoma, Southwestern Electric Power Company, and Wheeling Power Company (collectively, AEP)
American Forest & Paper Association (American Forest & Paper)
American Public Power Association (APPA)
American Wind Energy Association (AWEA)
ARIPPA
California Electricity Oversight Board (CEOB)
Calpine Corporation (Calpine)
CE Generation, LLC (CE Generation)
Cinergy Solutions, Inc. (Cinergy)
Cogeneration Association California jointly with Energy Producers and Users Coalition, Cogeneration Coalition of Washington, and Nevada Independent Energy Coalition (collectively, QF Parties)
Cogentrix Energy, inc. (Cogentrix) jointly with Goldman Sachs Group, Inc. (Goldman Sachs) (collectively, Independent Sellers)
Constellation Energy Group, Inc. (Constellation)
Council of Industrial Boiler Owners (CIBO)
Delta Power Company, LLC (Delta Power) jointly with Juniper Generation, LLC (Juniper), and California Cogeneration Council (California Cogen)
Department of Housing and Urban Development
Dow Chemical Company (Dow)
Edison Electric Institute (EEI)
Edison Mission Energy jointly with Edison Mission Marketing & Trading, Inc., Midwest Generation EME, LLC (collectively, Edison Mission Energy) (intervention only)
Electric Power Supply Association (EPSA)
Electricity Consumers Resource Council (ELCON) jointly with American Iron and Steel Institute (AISI) (collectively, Industrial Consumers)
Enel North America, Inc. (Enel)
Entergy Services, Inc. jointly with Entergy Arkansas, Inc.; Entergy Gulf States, Inc.; Entergy Louisiana, Inc.; Entergy Mississippi, Inc.; and Entergy New Orleans, Inc. (collectively, Entergy)
Environmental Protection Agency
The Fertilizer Institute (Fertilizer Institute)
Florida Industrial Cogeneration Association (Florida Industrial Cogeneration)
GE Energy Financial Services (GE)
Granite State Hydropower Association, Inc. (Granite State Hydropower)
Illinois Landfill Gas Coalition (Illinois Landfill Gas)
Indeck Energy Services, Inc. (Indeck)
Kentucky Public Service Commission (Kentucky Commission)
Marina Energy, LLC (Marina Energy)
National Association of Regulatory Utility Commissioners (NARUC)
National Rural Electric Cooperative Association (NRECA)
New York State Electric & Gas Corporation (NYSEG) jointly with Rochester Gas and Electric Corporation (Rochester G&E)
Non-Utility QF Group
North Carolina Eastern Municipal Power Agency (NCEMPA)
Occidental Chemical Corporation (Occidental)
Oklahoma Corporation Commission (Oklahoma Commission)
Oklahoma Gas and Electric Company (OG&E)
Pacific Gas and Electric Company (PG&E)
Primary Energy Ventures LLC (Primary Energy)
Process Gas Consumers Group Electricity Committee (Electricity Committee)
Progress Energy, Inc. (Progress Energy)
Public Service Company of New Mexico (PSNM) jointly with Texas-New Mexico Power Company (TNP)
Public Service Electric and Gas Company jointly with PSEG Power LLC, PSEG Energy Resources & Trade LLC, and PSEG Global L.L.C. (collectively, PSEG)
Public Utility Commission of Ohio (Ohio Commission)
Ridgewood Renewable Power, LLC (Ridgewood)
Solar Turbines Incorporated (Solar Turbines)
Southern California Edison Company (SoCal Edison)
Transmission Access Policy Study Group (TAPS)
U.S. Combined Heat and Power Association (USCHPA)
U.S. Environmental Protection Agency (EPA)
Xcel Energy Services Inc. (Xcel)
York County Solid Waste and Refuse Authority (York County)

[FR Doc. 06–1194 Filed 2–14–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR 870

[Docket No. 2005N–0506]

Medical Devices; Cardiovascular Devices; Classification of Implantable Intra-Aneurysm Pressure Measurement System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the implantable intra-aneurysm pressure measurement system 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 Intra-Aneurysm Pressure Measurement System.'' 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 announcing the availability of a guidance document that will serve as the special control for the device.

DATES: This rule is effective March 17, 2006.

FOR FURTHER INFORMATION CONTACT: Nelson Anderson, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8282, ext. 171.

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 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 the 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 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. 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 August 4, 2005, classifying the CardioMEMS EndoSensor System into 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 9, 2005, CardioMEMS, Inc., submitted a petition requesting classification of the CardioMEMS EndoSensor System under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with 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 the CardioMEMS EndoSensor System can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device type.

The device type is assigned the generic name Implantable Intra-Aneurysm Pressure Measurement System, and it is identified as a device intended to measure the intra-sac pressure in a vascular aneurysm. The device consists of a pressure transducer that is implanted into the aneurysm and a monitor that reads the pressure from the transducer.

FDA has identified the following risks to health associated specifically with this type of device: (1) Adverse tissue reaction, (2) the migration of implanted sensor, (3) inaccurate sensor information, (3) failure of implanted sensor, (4) failure of delivery system, (5) failure of electronic monitor, (6) electromagnetic interference, (7) electrical hazards, (8) magnetic resonance imaging incompatibility, (9) ultrasound incompatibility, (10) external defibrillation incompatibility, and (11) failure to detect and/or diagnose an endoleak that requires intervention.

FDA believes that the class II special controls guidance document entitled, ''Implantable Intra-Aneurysm Pressure Measurement System'' will aid in mitigating the potential risks to health by providing recommendations on biocompatibility testing, bench testing, software validation, electromagnetic compatibility testing, electrical safety testing, sterility of the device, magnetic resonance imaging compatibility, labeling, ultrasound compatibility, defibrillator compatibility, animal testing, and clinical testing. The guidance document also provides information on how to meet premarket (510(k)) submission requirements for the device. FDA believes that the special controls guidance document, in addition to general controls, addresses the risks to health identified previously and provides reasonable assurance of the safety and effectiveness of the device. Therefore, on October 28, 2005, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding § 870.2855 to its classification regulations.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for an implantable intra-aneurysm pressure measurement system will need to address the issues covered in the special controls 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.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirement under 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 implantable intra-aneurysm pressure measurement 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 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. What Is the Economic Impact of This Rule?

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 (Pub. L. 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 and so it 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. Because classification of this device in 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 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 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 $115 million, using the most current (2003) 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 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 collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also concludes that the special controls guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA.

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 CardioMEMS, Inc., dated August 9, 2005.

List of Subjects in 21 CFR Part 870

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 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

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

■ 2. Section 870.2855 is added to subpart C to read as follows:

§ 870.2855 Implantable Intra-aneurysm Pressure Measurement System.

(a) *Identification.* Implantable intra-aneurysm pressure measurement system is a device used to measure the intra-sac pressure in a vascular aneurysm. The device consists of a pressure transducer that is implanted into the aneurysm and a monitor that reads the pressure from the transducer.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System.'' See § 870.1 (e) for the availability of this guidance document.

Dated: February 6, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 06–1417 Filed 2–14–06; 8:45 am]

BILLING CODE 4160–01–S

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in March 2006. Interest assumptions are also published on the PBGC's Web site (*http://www.pbgc.gov*).

DATES: Effective March 1, 2006.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Attorney, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users should call the Federal relay service by dialing 711 and ask for 202–326–4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to Part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to Part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to Part 4022).

This amendment (1) adds to Appendix B to Part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during March 2006, (2) adds to Appendix B to Part 4022 the