variable tone emitting and fluorescence measurement functions. The intended use of the device is to aid in the detection of tooth decay by measuring increased laser induced fluorescence.

(b) *Classification*. Class II, subject to the following special controls:

(1) Sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter;

(2) Premarket notifications must include clinical studies, or other relevant information, that demonstrates that the device aids in the detection of tooth decay by measuring increased laser induced fluorescence; and

(3) The labeling must include detailed use instructions with precautions that urge users to:

(i) Read and understand all directions before using the device,

(ii) Store probe tips under proper conditions,

(iii) Properly sterilize the emitter-detector handpick before each use, and

(iv) Properly maintain and handle the instrument in the specified manner and condition.

Dated: March 29, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–8597 Filed 4–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 00P–1120]

Medical Devices; Gastroenterology-Urology Devices; Nonimplanted, Peripheral Electrical Continence Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the nonimplanted, peripheral electrical continence device into class II (special controls). The special controls that will apply to this device are set forth below. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying this device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective May 8, 2000.

FOR FURTHER INFORMATION CONTACT: Laura J. Byrd, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of 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 the 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), request FDA to classify the device under the criteria set forth in section 513(a)(1). 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.

On January 24, 2000, UroSurge, Inc., submitted a petition under section 513(f)(2) of the act requesting classification of its Percutaneous SANS Device intended for use in patients suffering from urinary urgency, frequency, or urge incontinence. After review of the information submitted in the petition and the premarket notification (K992069), FDA issued an order on February 9, 2000, classifying the UroSurge Percutaneous SANS (Stoller Afferent Nerve Stimulator) Device and substantially equivalent devices of this generic type into class II under the generic name, ''nonimplanted, peripheral nerve stimulator for pelvic floor dysfunction.'' FDA has determined that the nonimplanted, peripheral nerve stimulator for pelvic floor dysfunction can be classified in class II with the establishment of the following special controls:

1. That sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 (21 CFR 801.109).

2. That the labeling must bear all information required for the safe and effective use of the device as outlined in § 801.109(c), including a detailed summary of the clinical information upon which the instructions are based.

FDA believes that these class II special controls, in addition to the general controls, provide reasonable assurance of the safety and effectiveness of the device.

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 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the 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. 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. FDA knows of only one manufacturer of this type of device. The agency therefore certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

IV. 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.

List of Subjects in 21 CFR Part 876

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 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

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

2. Section 876.5310 is added to subpart F to read as follows:

§ 876.5310 Nonimplanted, peripheral electrical continence device.

(a) *Identification.* A nonimplanted, peripheral electrical continence device is a device that consists of an electrode that is connected by an electrical cable to a battery-powered pulse source. The electrode is placed onto or inserted into the body at a peripheral location and used to stimulate the nerves associated with pelvic floor function to maintain urinary continence. When necessary, the electrode may be removed by the user.

(b) *Classification.* Class II, subject to the following special controls:

(1) That sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) That the labeling must bear all information required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter, including a detailed summary of the clinical information upon which the instructions are based.

Dated: March 29, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–8596 Filed 4–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

[SPATS No. IL–097–FOR, Part III]

Illinois Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: OSM is approving part of an amendment to the Illinois regulatory program (Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Illinois proposed revisions to its program concerning subsidence control, water replacement, adjustment of performance bond amounts, administrative review, release of performance bonds, siltation structures, impoundments, hydrologic balance, disposal of noncoal mine wastes, revegetation, backfilling and grading, prime farmland, and State inspections. This final rule document addresses Illinois' revisions concerning release of performance bonds, siltation structures, impoundments, hydrologic balance, disposal of noncoal mine wastes, revegetation, backfilling and grading, and prime farmland. We addressed the remaining program topics in two previous final rule documents. Illinois intends to revise its program to be consistent with the corresponding Federal regulations, to provide additional safeguards, and to improve operational efficiency.

EFFECTIVE DATE: April 7, 2000.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204–1521. Telephone: (317) 226–6700. Internet: INFOMAIL@indgw.osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Illinois Program
II. Submission of the Amendment
III. Director's Findings
IV. Summary and Disposition of Comments
V. Director's Decision
VI. Procedural Determinations

I. Background on the Illinois Program

On June 1, 1982, the Secretary of the Interior conditionally approved the Illinois program. You can find background information on the Illinois program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the June 1, 1982, **Federal Register** (47 FR 23883). You can find later actions concerning the Illinois program and previous amendments at 30 CFR 913.15, 913.16, and 913.17.

II. Submission of the Proposed Amendment

By letter dated August 2, 1999 (Administrative Record No. IL–5044), the Illinois Department of Natural Resources (Department) submitted an amendment to the Illinois program under the Federal regulations at 30 CFR 732.17(b). The Department proposed to amend Title 62 of the Illinois Administrative Code (IAC) in response to our letters dated May 20, 1996, June 17, 1997, October 30, 1997, and January 15, 1999 (Administrative Record Nos. IL–1900, IL–2000, IL–2002, and IL–5036, respectively), that we sent to Illinois under 30 CFR 732.17(c). The amendment also includes changes made at the Department's own initiative.

We announced receipt of the amendment in the August 17, 1999, **Federal Register** (64 FR 44674). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. The public comment period closed on September 16, 1999. No one requested an opportunity to speak at a public hearing, so no hearing was held.

During our review of the amendment, we identified concerns relating to siltation structures, impoundments, performance bonds, and State inspections. We also identified some nonsubstantive editorial errors. We notified Illinois of these concerns and editorial errors by letter dated September 21, 1999 (Administrative Record No. IL–5048). We also separated the amendment into three parts in order to expedite the State program amendment process. Part I concerned revisions to Illinois' regulations relating to subsidence control and water replacement. Because we did not identify any concerns relating to Illinois' revisions for subsidence control and water replacement, we made our final decision on them in a final rule on