JURISDICTION	☐ Arkansas ☐ California ☐ Colorado ☐ Connecticut ☐ Delaware ☐ District of Columbia ☐ Florida ☐ Georgia	☐ Indiana ☐ Iowa ☐ Kansas ☐ Kentucky ☐ Louisiana ☐ Maine ☐ Maryland ☐ Massachusetts	☐ Missouri ☐ Montana ☐ Nebraska ☐ Nevada ☐ New Hampshire ☐ New Jersey ☐ New Mexico ☐ New York	☐ Oklahoma ☐ Oregon ☐ Pennsylvania ☐ Puerto Rico ☐ Rhode Island ☐ South Carolina ☐ South Dakota ☐ Tennessee	☐ Virgin Islands ☐ Virginia ☐ Washington ☐ West Virginia ☐ Wisconsin ☐ Wyoming

* * * * *

■ 3. Form BDW (referenced in § 249.501a) is amended by:

■ a. In the Explanation of Terms section, revising ''The term JURISDICTION means a state, the District of Columbia, the Commonwealth of Puerto Rico, or any subdivision or regulatory body thereof.'' to read ''The term JURISDICTION means a state, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, or any subdivision or regulatory body thereof.''; and

■ b. In Item 3, revising the SRO and Jurisdiction tables.

The revision reads as follows:

Form BDW

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3. * * *

SRO	☐ AMEX	☐ BSE	☐ CBOE	☐ CHX	☐ NSX	☐ NASD	☐ NQX	☐ NYSE	☐ PHLX	☐ ARCA	☐ ISE	☐_____ OTHER (specify)

JURISDICTION	☐ Alabama ☐ Alaska ☐ Arizona ☐ Arkansas ☐ California ☐ Colorado ☐ Connecticut ☐ Delaware ☐ District of Columbia ☐ Florida ☐ Georgia	☐ Hawaii ☐ Idaho ☐ Illinois ☐ Indiana ☐ Iowa ☐ Kansas ☐ Kentucky ☐ Louisiana ☐ Maine ☐ Maryland ☐ Massachusetts	☐ Michigan ☐ Minnesota ☐ Mississippi ☐ Missouri ☐ Montana ☐ Nebraska ☐ Nevada ☐ New Hampshire ☐ New Jersey ☐ New Mexico ☐ New York	☐ North Carolina ☐ North Dakota ☐ Ohio ☐ Oklahoma ☐ Oregon ☐ Pennsylvania ☐ Puerto Rico ☐ Rhode Island ☐ South Carolina ☐ South Dakota ☐ Tennessee	☐ Texas ☐ Utah ☐ Vermont ☐ Virgin Islands ☐ Virginia ☐ Washington ☐ West Virginia ☐ Wisconsin ☐ Wyoming

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By the Commission.

Dated: April 19, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7746 Filed 4–23–07; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 2007N–0120]

Medical Devices; Obstetrical and Gynecological Devices; Classification of Computerized Labor Monitoring System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the computerized labor monitoring 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 FDA Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems,'' which will serve as the special controls for these devices. The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of these devices.

DATES: This rule is effective May 24, 2007. The classification was effective January 30, 2007.

FOR FURTHER INFORMATION CONTACT: Glenn Bell, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4100.

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 October 5, 2006, classifying the Computerized

Labor Monitoring 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. Barnev Ltd. submitted a petition dated October 15, 2006, requesting classification of the Computerized Labor Monitoring 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 computerized labor monitoring 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 ''Computerized Labor Monitoring System.'' It is identified as a system intended to continuously measure cervical dilation and fetal head descent and provide a display that indicates the progress of labor. The computerized labor monitoring system includes a monitor and ultrasound transducers. Ultrasound transducers are placed on the maternal abdomen and cervix and on the fetal scalp to provide the matrix of measurements used to produce the display.

FDA has identified the risks to health associated with this type of device as—

A. Patient Injury—tissue injury or bleeding to baby or mother

B. Electrical Hazards—electrical shock

C. Acoustical (ultrasound) Tissue Damage—acoustical heating of tissue due to ultrasound

D. Electromagnetic Interference and Electrostatic Discharge Hazards—electromagnetic emissions interfering with other medical devices or electromagnetic susceptibility causing the device to function improperly due to emissions of other devices

E. Mismanagement of Patient—unattended birth or improper clinical decisions based on device output information

F. Adverse Tissue Reaction—adverse tissue reaction to bio-incompatible materials

G. Infection - bacterial, viral, or fungal infection of baby or mother

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	Mitigation Measures
Patient Injury	Nonclinical Analysis and Testing Software Clinical Information Labeling
Electrical Hazards	Nonclinical Analysis and Testing Electrical Safety Labeling
Acoustical (ultrasound) Tissue Damage	Nonclinical Analysis and Testing Ultrasound Safety Labeling
Electromagnetic Interference and Electrostatic Discharge Hazards	Electromagnetic Compatibility Labeling
Mismanagement of Patient	Nonclinical Analysis and Testing Software Clinical Information Labeling
Adverse Tissue Reaction	Biocompatibility
Infection	Sterilization Information

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 January 30, 2007, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification at 21 CFR 884.2800.

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 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 computerized

labor monitoring 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 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 not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of 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 $122 million, using the most current (2005) 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.

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 Barnev Ltd., dated October 15, 2006.

List of Subjects in 21 CFR Part 884

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 884 is amended as follows:

PART 884–OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 884 continues to read as follows:

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

■ 2. Section 884.2800 is added to subpart C to read as follows:

§ 884.2800 Computerized Labor Monitoring System.

(a) *Identification.* A computerized labor monitoring system is a system intended to continuously measure cervical dilation and fetal head descent and provide a display that indicates the progress of labor. The computerized labor monitoring system includes a monitor and ultrasound transducers. Ultrasound transducers are placed on the maternal abdomen and cervix and on the fetal scalp to provide the matrix of measurements used to produce the display.

(b) *Classification.* Class II (special controls). The special controls are the FDA guidance document entitled: ''Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems.'' See § 884.1(e) for availability of this guidance document.

Dated: April 13, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–7702 Filed 4–23–07; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0093; FRL–8304–2]

RIN 2060–AN10

National Emission Standards for Hazardous Air Pollutants: Surface Coating of Automobiles and Light-Duty Trucks; National Emission Standards for Hazardous Air Pollutants for Surface Coating of Plastic Parts and Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on amendments to the National Emission Standards for Hazardous Air Pollutants: Surface Coating of Automobiles and Light-Duty Trucks (Automobiles and Light-Duty Trucks NESHAP) which were promulgated on April 26, 2004, under the authority of section 112(d) of the Clean Air Act. The direct final rule amends provisions in the Automobiles and Light-Duty Trucks NESHAP to clarify the interaction between the Automobiles and Light-Duty Trucks NESHAP and the National Emission Standards for Hazardous Air Pollutants for Surface Coating of Plastic Parts and Products (Plastic Parts NESHAP), to clarify the meaning of certain regulatory provisions, and to correct certain errors identified in the regulatory text. EPA is also taking direct final action on amendments to the Plastic Parts NESHAP to clarify that screen printing is not subject to that rule.

DATES: The direct final rule is effective on June 25, 2007 without further notice,