information collection, communication and management within the energy industry. The Commission has assured itself, by means of internal review, that there is specific, objective support for the burden estimates associated with the information requirements.

Interested persons may obtain information on the reporting requirements by contacting: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: *DataClearance@ferc.gov*, Phone: (202) 502–8663, fax: (202) 273–0873]. Comments on the requirements of this rule may also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission]. For security reasons, comments should be sent by email to OMB at *oira_submission@omb.eop.gov.* Comments submitted to OMB should refer to FERC–725L and OMB Control No. 1902–0261.

V. Regulatory Flexibility Act Certification

24. The Regulatory Flexibility Act of 1980 (RFA) [21] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities.

25. The Small Business Administration (SBA) revised its size standard (effective January 22, 2014) for electric utilities from a standard based on megawatt hours to a standard based on the number of employees, including affiliates.[22] Under SBA's new size standards, transmission owners and transmission operators likely come under the following category and associated size threshold: Electric bulk power transmission and control, at 500 employees.[23] The Reliability Standard applies to 561 entities. Comparison of the applicable entities with the Commission's small business data indicates that approximately 249 are small entities.[24] Of these, the Commission estimates that approximately five percent, or twelve of these small entities expect to be affected by the new requirements of the proposed Reliability Standard. The Commission estimates that the small entities that will be affected by Reliability Standard MOD–031–1 will incur one-time compliance costs ranging up to $14,309 (*i.e.* the cost of determining the method of weather normalizing annual peak hour actual demand), plus the annual development of summary narratives in accordance with Requirement R1, Subparts 1.5.4 and 1.5.5, resulting in costs of $477.

26. Accordingly, the Commission certifies that the Reliability Standard will not have a significant economic impact on a substantial number of small entities.

VI. Environmental Analysis

27. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[25] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.[26] The actions proposed herein fall within this categorical exclusion in the Commission's regulations.

VII. Document Availability

28. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

29. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

30. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VIII. Effective Date and Congressional Notification

31. These regulations are effective April 27, 2015. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

By the Commission.

Issued: February 19, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–03740 Filed 2–23–15; 8:45 am]

BILLING CODE 6717–01–P

[21] 5 U.S.C. 601–612.

[22] SBA Final Rule on ''Small Business Size Standards: Utilities,'' 78 FR 77,343 (Dec. 23, 2013).

[23] 13 CFR 121.201, Sector 22, Utilities.

[24] The Small Business Administration sets the threshold for what constitutes a small business. Public utilities may fall under one of several different categories, each with a size threshold based on the company's number of employees, including affiliates, the parent company, and subsidiaries. The possible categories for the applicable entities have a size threshold ranging from 250 employees to 1,000 employees. For the analysis in this proposed rule, we are using the 1,000 employee threshold for each applicable entity type.

[25] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (1987).

[26] 18 CFR 380.4(a)(2)(ii).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2014–N–1903]

Medical Devices; Physical Medicine Devices; Classification of the Powered Exoskeleton

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the powered exoskeleton into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the powered exoskeleton's classification. 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.

DATES: This order is effective March 26, 2015. The classification was applicable on June 26, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Hoffmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1434, Silver Spring, MD 20993–0002, 301–796–6476, *Michael.Hoffmann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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), 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 FD&C 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 FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On June 22, 2013, Argo Medical Technologies, Inc., submitted a request for classification of the ReWalk under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices 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 request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 26, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 890.3480.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a powered exoskeleton will need to comply with the special controls named in this final order. The device is assigned the generic name powered exoskeleton, and it is identified as a prescription device that is composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation.

FDA has identified the following risks to health associated specifically with this type of device, as well as the measures required to mitigate these risks in table 1.

TABLE 1—POWERED EXOSKELETON RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Instability, falls, and associated injuries	Clinical testing. Training. Software verification, validation, and hazard analysis. Wireless testing. Electromagnetic compatibility (EMC) and electromagnetic interference (EMI) testing. Electrical safety testing. Design characteristics. Non-clinical performance testing. Water/particle ingress testing. Durability testing. Battery testing. Labeling.
Bruising, skin abrasion, pressure sores, soft tissue injury	Clinical testing. Training. Labeling.
Diastolic hypertension and changes in blood pressure, and heart rate	Clinical testing. Training. Labeling.
Adverse tissue reaction	Biocompatibility assessment.
Premature battery failure	Battery testing. Labeling.
Interference with other electrical equipment/devices	EMC/EMI testing. Labeling.

TABLE 1—POWERED EXOSKELETON RISKS AND MITIGATION MEASURES—Continued

Identified risk	Mitigation measure
Burns, electrical shock	Electrical safety testing. Thermal testing. Labeling.
Device malfunction resulting in unanticipated operation (e.g., device stoppage, unintended movement).	Clinical testing. Non-clinical performance testing. Training. Software verification, validation, and hazard analysis. Electrical safety testing. Battery testing. Water/particle ingress testing. Wireless testing. EMC/EMI testing. Flammability testing. Labeling.
Use error	Clinical testing. Training. Labeling.

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

- Elements of the device materials that may contact the patient must be demonstrated to be biocompatible.
- Appropriate analysis/testing must validate electronic compatibility/interference (EMC/EMI), electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.
- Appropriate software verification, validation, and hazard analysis must be performed.
- Design characteristics must ensure geometry and materials composition are consistent with intended use.
- Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:
  - Mechanical bench testing (including durability testing) to demonstrate that the device will withstand forces, conditions, and environments encountered during use;
  - simulated use testing (*i.e.,* cyclic loading testing) to demonstrate performance of device commands and safeguard under worst case conditions and after durability testing;
  - verification and validation of manual override controls are necessary, if present;
  - the accuracy of device features and safeguards; and
  - device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor performance.
- Clinical testing must demonstrate safe and effective use and capture any adverse events observed during clinical use when used under the proposed conditions of use, which must include considerations for:
  - Level of supervision necessary and
  - environment of use (*e.g.,* indoors and/or outdoors), including obstacles and terrain representative of the intended use environment.
- A training program must be included with sufficient educational elements so that upon completion of training program, the clinician, user, and companion can:
  - Identify the safe environments for device use,
  - use all safety features of device, and
  - operate the device in simulated or actual use environments representative of indicated environments and use.
- Labeling for the Physician and User must include the following:
  - Appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities and environments that may put the user at greater risk;
  - specific instructions and the clinical training needed for the safe use of the device, which includes:
    - Instructions on assembling the device in all available configurations;
    - instructions on fitting the patient;
    - instructions and explanations of all available programs and how to program the device;
    - instructions and explanation of all controls, input, and outputs;
    - instructions on all available modes or states of the device;
    - instructions on all safety features of the device; and
    - instructions for properly maintaining the device;
  - Information on the patient population for which the device has been demonstrated to have a reasonable assurance of safety and effectiveness;
  - pertinent non-clinical testing information (*e.g.,* EMC, battery longevity); and
  - a detailed summary of the clinical testing including:
    - Adverse events encountered under use conditions,
    - summary of study outcomes and endpoints, and
    - information pertinent to use of the device including the conditions under which the device was studied (*e.g.,* level of supervision or assistance, and environment of use (*e.g.,* indoors and/or outdoors) including obstacles and terrain).

Powered exoskeleton devices are restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see section 520(e) of the FD&C Act (21 U.S.C. 360j(e)) and 21 CFR 801.109 (*Prescription devices*). Prescription-use restrictions are a type of general controls as defined in section 513(a)(1)(A)(i) of the FD&C Act.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C 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. Therefore, this device type 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 powered exoskeleton they intend to market.

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. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

IV. Reference

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, and is available electronically at *http://www.regulations.gov*.

1. K131798: De Novo Request per 513(f)(2) from Argo Medical Technologies, Inc., dated June 22, 2013.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for 21 CFR part 890 continues to read as follows:

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

■ 2. Add § 890.3480 to subpart D to read as follows:

§ 890.3480 Powered exoskeleton.

(a) *Identification.* A powered exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Elements of the device materials that may contact the patient must be demonstrated to be biocompatible.

(2) Appropriate analysis/testing must validate electromagnetic compatibility/interference (EMC/EMI), electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.

(3) Appropriate software verification, validation, and hazard analysis must be performed.

(4) Design characteristics must ensure geometry and materials composition are consistent with intended use.

(5) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:

(i) Mechanical bench testing (including durability testing) to demonstrate that the device will withstand forces, conditions, and environments encountered during use;

(ii) Simulated use testing (*i.e.,* cyclic loading testing) to demonstrate performance of device commands and safeguard under worst case conditions and after durability testing;

(iii) Verification and validation of manual override controls are necessary, if present;

(iv) The accuracy of device features and safeguards; and

(v) Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor performance.

(6) Clinical testing must demonstrate safe and effective use and capture any adverse events observed during clinical use when used under the proposed conditions of use, which must include considerations for:

(i) Level of supervision necessary, and

(ii) Environment of use (*e.g.,* indoors and/or outdoors) including obstacles and terrain representative of the intended use environment.

(7) A training program must be included with sufficient educational elements so that upon completion of training program, the clinician, user, and companion can:

(i) Identify the safe environments for device use,

(ii) Use all safety features of device, and

(iii) Operate the device in simulated or actual use environments representative of indicated environments and use.

(8) Labeling for the Physician and User must include the following:

(i) Appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities and environments that may put the user at greater risk.

(ii) Specific instructions and the clinical training needed for the safe use of the device, which includes:

(A) Instructions on assembling the device in all available configurations;

(B) Instructions on fitting the patient;

(C) Instructions and explanations of all available programs and how to program the device;

(D) Instructions and explanation of all controls, input, and outputs;

(E) Instructions on all available modes or states of the device;

(F) Instructions on all safety features of the device; and

(G) Instructions for properly maintaining the device.

(iii) Information on the patient population for which the device has been demonstrated to have a reasonable assurance of safety and effectiveness.

(iv) Pertinent non-clinical testing information (*e.g.,* EMC, battery longevity).

(v) A detailed summary of the clinical testing including:

(A) Adverse events encountered under use conditions,

(B) Summary of study outcomes and endpoints, and

(C) Information pertinent to use of the device including the conditions under which the device was studied (*e.g.,* level of supervision or assistance, and environment of use (*e.g.,* indoors and/or outdoors) including obstacles and terrain).

Dated: February 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03692 Filed 2–23–15; 8:45 am]

BILLING CODE 4164–01–P