XI. Effective Date

The preamble to the proposed rule stated that a final rule deeming that any seasonal and decorative lighting product that does not conform to sections 6, 7, 15, 71, 79, and SB15 of UL 588 with regard to minimum wire size, sufficient strain relief, and overcurrent protection is a substantial product hazard would take effect 30 days after publication of the rule in the **Federal Register**. We received no comments on the effective date. Accordingly, the final rule will apply to seasonal and decorative lighting products imported or introduced into commerce on June 3, 2015.

List of Subjects in 16 CFR Part 1120

Administrative practice and procedure, Clothing, Consumer protection, Household appliances, Imports, Incorporation by reference, Infants and children, Lighting.

For the reasons stated above, and under the authority of 15 U.S.C. 2064(j), 5 U.S.C. 553, and section 3 of Public Law 110–314, 122 Stat. 3016 (August 14, 2008), the Consumer Product Safety Commission amends 16 CFR part 1120 to read as follows:

PART 1120—SUBSTANTIAL PRODUCT HAZARD LIST

■ 1. The authority citation for part 1120 continues to read as follows:

Authority: 15 U.S.C. 2064(j).

■ 2. In § 1120.2, add paragraph (d) to read as follows:

§ 1120.2 Definitions.

* * * * *

(d) *Seasonal and decorative lighting product* means portable, plug-connected, temporary-use lighting products and accessories that have a nominal 120 volt input voltage rating. Lighting products within the scope of the rule are factory-assembled with push-in, midget- or miniature-screw base lampholders connected in series or with candelabra- or intermediate-screw base lampholders connected in parallel, directly across the 120 volt input. Such lighting products include lighted decorative outfits, such as stars, wreathes, candles without shades, light sculptures, blow-molded (plastic) figures, and animated figures. Lighting products outside the scope of the rule include: Battery-operated products; solar-powered products; products that operate from a transformer or low-voltage power supply; flexible lighting products incorporating non-replaceable series and series/parallel connected lamps enclosed within a flexible polymeric tube or extrusion; and portable electric lamps that are used to illuminate seasonal decorations.

■ 3. In § 1120.3, republish the introductory text, revise paragraphs (a) and (b)(1), and add paragraph (c), to read as follows:

§ 1120.3 Products deemed to be substantial product hazards.

The following products or class of products shall be deemed to be substantial product hazards under section 15(a)(2) of the CPSA:

(a) Hand-supported hair dryers that do not provide integral immersion protection in compliance with the requirements of section 5 of UL 859, or section 6 of UL 1727 (incorporated by reference, *see* § 1120.4).

(b)(1) Children's upper outerwear in sizes 2T to 16 or the equivalent, and having one or more drawstrings, that is subject to, but not in conformance with, the requirements of ASTM F 1816–97 (incorporated by reference, *see* § 1120.4).

* * * * *

(c) Seasonal and decorative lighting products that lack one or more of the following characteristics in conformance with requirements in sections 6, 7, 15, 71, 79, and SB15 of UL 588 (incorporated by reference, see § 1120.4):

(1) Minimum wire size requirements in section 6 of UL 588;

(2) Sufficient strain relief requirements in sections 15, 71, 79, and SB15 of UL 588; or

(3) Overcurrent protection requirements in section 7 of UL 588.

■ 4. Add § 1120.4 to read as follows:

§ 1120.4 Standards incorporated by reference.

(a) The standards required in this part are incorporated by reference (''IBR'') into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect all approved material at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (''NARA''). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(b) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA, telephone: 610–832–9585; *http://www2.astm.org/*.

(1) ASTM F 1816–97, *Standard Safety Specification for Drawstrings on Children's Upper Outerwear,* approved June 10, 1997, published August 1998 (''ASTM F 1816–97''), IBR approved for § 1120.3(b).

(2) [Reserved]

(c) Underwriters Laboratories, Inc (''UL''), 333 Pfingsten Road, Northbrook, IL 60062 or through UL's Web site: *www.UL.com*.

(1) UL 588, *Standard for Safety for Seasonal and Holiday Decorative Products,* 18th Edition, approved August 21, 2000 (''UL 588''), IBR approved for § 1120.3(c).

(2) UL 859, *Standard for Safety for Household Electric Personal Grooming Appliances,* 10th Edition, approved August 30, 2002, and revised through June 3, 2010 (''UL 859''), IBR approved for § 1120.3(a).

(3) UL 1727, *Standard for Safety for Commercial Electric Personal Grooming Appliances,* 4th Edition, approved March 25, 1999, and revised through June 25, 2010 (''UL 1727''), IBR approved for § 1120.3(a).

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2015–10342 Filed 5–1–15; 8:45 am]

BILLING CODE 6355–01–P

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 Lower Extremity Exoskeleton; Republication

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order; republication.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is republishing in its entirety a final order entitled ''Medical Devices; Physical Medicine Devices; Classification of the Powered Lower Extremity Exoskeleton'' that published in the **Federal Register** on February 24, 2015. FDA is republishing to correct an inadvertent omission of information. FDA is classifying the powered lower extremity 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 lower extremity 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 May 4, 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 (Pub. L. 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 lower extremity exoskeleton will need to comply with the special controls named in this final order. The device is assigned the generic name powered lower extremity exoskeleton, and it is identified as a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes.

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 LOWER EXTREMITY 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

TABLE 1—POWERED LOWER EXTREMITY EXOSKELETON RISKS AND MITIGATION MEASURES—Continued

Identified risk	Mitigation measure
Adverse tissue reaction	Labeling Biocompatibility assessment
Premature battery failure	Battery testing Labeling
Interference with other electrical equipment/devices	EMC/EMI testing Labeling
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 a reasonable assurance of 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 lower extremity exoskeleton devices are restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription devices*).

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 lower extremity 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. Revise § 890.3480 to read as follows:

§ 890.3480 Powered lower extremity exoskeleton.

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

(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 a reasonable assurance of 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: April 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10332 Filed 5–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9708]

RIN 1545–BK57; RIN 1545–BL30; RIN 1545–BL58

Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable; Requirements of a Section 4959 Excise Tax Return and Time for Filing the Return; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 9708) that were published in the **Federal Register** on December 31, 2014 (79 FR 78954). The final regulations provide guidance regarding the requirements for charitable hospital organizations added by the Patient Protection and Affordable Care Act of 2010.

DATES: This correction is effective on May 4, 2015 and applicable beginning December 31, 2014.

FOR FURTHER INFORMATION CONTACT: Amy F. Giuliano, Amber L. MacKenzie, or Stephanie N. Robbins at (202) 317–5800 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9708) that are the subject of this correction is under section 501 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9708) contain an error that may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.6033–2 is amended by revising paragraph (k)(4) to read as follows:

§ 1.6033–2 Return by exempt organizations (taxable years beginning after December 31, 1969) and returns by certain nonexempt organizations (taxable years beginning after December 31, 1980).

* * * * *

(k) * * *

(4) The applicability of paragraph (a)(2)(ii)(*l*) of this section shall be limited to returns filed for taxable years ending after December 29, 2014.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2015–10340 Filed 5–1–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 53, and 602

[TD 9708]

RIN 1545–BK57; RIN 1545–BL30; RIN 1545–BL58

Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable; Requirements of a Section 4959 Excise Tax Return and Time for Filing the Return; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations; correction.

SUMMARY: This document contains corrections to final regulations (TD 9708) that were published in the **Federal Register** on December 31, 2014 (79 FR 78954). The final regulations provide guidance regarding the requirements for charitable hospital organizations added by the Patient Protection and Affordable Care Act of 2010.

DATES: This correction is effective on May 4, 2015 and applicable beginning December 31, 2014.

FOR FURTHER INFORMATION CONTACT: Amy F. Giuliano, Amber L. MacKenzie, or Stephanie N. Robbins at (202) 317–5800 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9708) that are the subject of this correction are under section 501 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9708) contain an error that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the final regulations (TD 9708), that are the subject of FR Doc. 2014–30525, are corrected as follows:

1. On page 78996, in the preamble, the first column, under the paragraph heading ''Effective/Applicability Dates'', the second line from the bottom of the third full paragraph, the language ''6033 apply to returns filed on or after'' is corrected to read ''6033 apply to returns filed for taxable years ending after''.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2015–10341 Filed 5–1–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 320

[Docket ID: DoD–2014–OS–0068]

Privacy Act; Implementation

AGENCY: National Geospatial-Intelligence Agency (NGA), DoD.

ACTION: Direct final rule with request for comments.

SUMMARY: National Geospatial-Intelligence Agency (NGA) is updating the NGA Privacy Act Program by adding the (k)(2) and (k)(5) exemptions to accurately describe the basis for exempting the records in the system of records notice NGA–010, National Geospatial-Intelligence Agency Security Financial Disclosure Reporting Records System. In this rulemaking, the NGA proposes to exempt portions of this system of records from one or more provisions of the Privacy Act because of criminal, civil and administrative enforcement requirements.

DATES: The rule will be effective on July 13, 2015 unless adverse comments are received by July 6, 2015. If adverse comment is received, the Department of Defense will publish a timely