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


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:


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, wreaths, 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):

* * * * *

(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, wreaths, 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.

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: 610–632–9585; http://www.astm.org/.


(2) [Reserved]

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


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 20932–0002, 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(f) 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, 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>
<thead>
<tr>
<th>Identified risk</th>
<th>Mitigation measure</th>
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<td>Instability, falls, and associated injuries</td>
<td>Clinical testing</td>
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<td>Training</td>
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<td>Software verification, validation, and hazard analysis</td>
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<td>Wireless testing</td>
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<td>Diastolic hypertension and changes in blood pressure, and heart rate</td>
<td>Electromagnetic compatibility (EMC) and electromagnetic interference (EMI) testing</td>
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<td>Electrical safety testing</td>
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<td>Design characteristics</td>
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<td>Non-clinical performance testing</td>
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<td>Water/particle ingress testing</td>
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<td>Clinical testing</td>
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</table>

Bruising, skin abrasion, pressure sores, soft tissue injury

Water/particle ingress testing

Durability testing

Battery testing

Labeling

Clinical testing

Training

Labeling

Clinical testing

Training

TABLE 1—POWERED LOWER EXTREMITY EXOSKELETON RISKS AND MITIGATION MEASURES
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;
  - 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).

Paragraph 916.200 of the FDA regulations provides that the clearance procedures for 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
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 808,
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
good 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).
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 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. 2015–10340 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).

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 320


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