(iii) Reliability.

(4) All patient contacting components of the device must be demonstrated to be biocompatible.

(5) Performance testing must demonstrate the electrical safety and electromagnetic compatibility (EMC) of any electrical components.

(6) Software validation, verification, and hazard analysis must be performed.

(7) Performance testing must demonstrate the sterility of all patient-contacting components.

(8) Performance testing must support the shelf life of the device by demonstrating continued sterility and device functionality over the identified shelf life.

(9) Labeling must include the following:

(i) A detailed summary of the non-clinical and in vivo evaluations pertinent to use of the device and accessories in the circuit;

(ii) Adequate instructions with respect to circuit setup, performance characteristics with respect to compatibility among different devices and accessories in the circuit, and maintenance during a procedure; and

(iii) A shelf life.

Dated: December 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28168 Filed 12–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2022–N–3144]

Medical Devices; Orthopedic Devices; Classification of the Resorbable Implant for Anterior Cruciate Ligament (ACL) Repair

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the resorbable implant for anterior cruciate ligament (ACL) repair into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the resorbable implant for ACL repair's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 29, 2022. The classification was applicable on December 16, 2020.

FOR FURTHER INFORMATION CONTACT: Pooja Panigrahi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4572, Silver Spring, MD 20993–0002, 240–402–1090, *Pooja.Panigrahi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the resorbable implant for ACL injuries as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 4, 2020, FDA received Miach Orthopaedics, Inc.'s request for De Novo classification of the BEAR® (Bridge-Enhanced ACL Repair) Implant. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C.

360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 16, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 888.3044.[1] We have named the generic type of device resorbable implant for ACL repair, and it is identified as a degradable material that allows for healing of a torn ACL that is biomechanically stabilized by traditional suturing procedures. The device is intended to protect the biological healing process from the surrounding intraarticular environment and not intended to replace biomechanical fixation via suturing. This classification includes devices that bridge or surround the torn ends of a ruptured ACL.

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

TABLE 1—RESORBABLE IMPLANT FOR ANTERIOR CRUCIATE LIGAMENT (ACL) REPAIR RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Repaired ACL has inadequate durability, leading to re-tear	Animal testing, Clinical performance testing, and Labeling.
Repaired ACL is loose or functionally limited, leading to joint instability	Clinical performance testing.
ACL does not heal due to inadequate resorption or migration of implant	Non-clinical performance testing and Animal testing.
Adverse tissue reaction	Biocompatibility evaluation and Labeling.
Infection	Sterilization validation, Shelf-life testing, and Labeling.
Febrile response due to endotoxins	Pyrogenicity testing.
Implant is incompatible with other ACL repair instrumentation and sutures, leading to inability to complete surgery.	Non-clinical performance testing and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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. 3501–3521). The collections of information in 21 CFR part 860, subpart D regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

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 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

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

■ 2. Add § 888.3044 to subpart D to read as follows:

§ 888.3044 Resorbable implant for anterior cruciate ligament (ACL) repair.

(a) *Identification.* A resorbable implant for anterior cruciate ligament (ACL) repair is a degradable material that allows for healing of a torn ACL that is biomechanically stabilized by traditional suturing procedures. The device is intended to protect the biological healing process from the surrounding intraarticular environment and not intended to replace biomechanical fixation via suturing. This classification includes devices that bridge or surround the torn ends of a ruptured ACL.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Post-operative evaluation of knee pain and function; and

(ii) Durability as assessed by re-tear or re-operation rate.

(2) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Device performance characteristics, including resorption and ligament healing at repair site; and

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

(ii) Adverse effects as assessed by gross necropsy and histopathology.

(3) Non-clinical testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Characterization of materials, including chemical composition, resorption profile, and mechanical properties; and

(ii) Simulated use testing, including device preparation, device handling, compatibility with other ACL repair instrumentation, and user interface.

(4) The device must be demonstrated to be biocompatible.

(5) Performance data must demonstrate the device to be sterile and non-pyrogenic.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(7) Labeling must include the following:

(i) Identification of device materials and specifications;

(ii) A summary of the clinical performance testing conducted with the device;

(iii) Instructions for use, including compatibility with other ACL repair instrumentation or devices;

(iv) Warnings regarding post-operative rehabilitation requirements; and

(v) A shelf life.

Dated: December 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28166 Filed 12–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9971]

RIN 1545–BN89

Exception for Interests Held by Foreign Pension Funds

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations regarding gain or loss of a qualified foreign pension fund attributable to certain interests in United States real property. The final regulations also include rules for certifying that a qualified foreign pension fund is not subject to withholding on certain dispositions of, and distributions with respect to, certain interests in United States real property. The final regulations affect certain holders of interests in United States real property and withholding agents that are required to withhold tax on dispositions of, and distributions with respect to, such property.

DATES: Effective Date: These regulations are effective on December 29, 2022.

Applicability dates: For dates of applicability, see §§ 1.897(l)–1(g), 1.1441–3(c)(4)(iii), 1.1445–2(e), 1.1445–5(h), 1.1445–8(j), 1.1446–7.

FOR FURTHER INFORMATION CONTACT: Arielle M. Borsos or Milton Cahn at (202) 317–6937 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 897(l) was added to the Internal Revenue Code (the ''Code'') by section 323(a) of the Protecting Americans from Tax Hikes Act of 2015, Public Law 114–113, div. Q (the ''PATH Act''), and amended by section 101(q) of the Tax Technical Corrections Act of 2018, Pub. L. 115–141, div. U. In the preamble to the updated section 1445 regulations that were published in the **Federal Register** (81 FR 8398–01, as corrected at 81 FR 24484–01) on February 19, 2016, the Department of the Treasury (the ''Treasury Department'') and the IRS requested comments regarding what regulations, if any, should be issued pursuant to section 897(l)(3). The Treasury Department and the IRS considered all of the comments received in response to this request and, on June 7, 2019, published proposed regulations under sections 897(l), 1441, 1445 and 1446 in the **Federal Register** (84 FR 26605) (the ''proposed regulations''). The proposed regulations contained rules relating to the qualification for the exemption under section 897(l), as well as rules relating to withholding requirements under sections 1441, 1445 and 1446, for dispositions of United States real property interests (''USRPIs'') by foreign pension funds and their subsidiaries and distributions described in section 897(h).

This Treasury decision finalizes the proposed regulations, after taking into account and addressing comments received by the Treasury Department and the IRS with respect to the proposed regulations. Terms used but not defined in this preamble have the meaning provided in the final regulations.

Comments outside the scope of this rulemaking are generally not addressed but may be considered in connection with future regulations. All written comments received in response to the proposed regulations are available at *www.regulations.gov* or upon request.

Summary of Comments and Explanation of Revisions

The final regulations retain the general approach and structure of the proposed regulations, with certain revisions. This Summary of Comments and Explanation of Revisions section discusses the revisions as well as comments received in response to the solicitation of comments in the proposed regulations.

I. Comments and Revisions Related to the Scope of the Exception

A. Qualified Controlled Entities

Under the proposed regulations, and consistent with section 897(l), gain or loss of a qualified foreign pension fund (''QFPF'') or a qualified controlled entity (''QCE'') (under the proposed regulations, each generally a ''qualified holder'') from the disposition of a USRPI is not subject to section 897(a). Prop. § 1.897(l)–1(b)(1). The proposed regulations defined a QCE as a trust or corporation organized under the laws of a foreign country,[1] all of the interests of which are held directly by one or more QFPFs or indirectly through one or more QCEs or partnerships. Prop. § 1.897(l)–1(d)(9).

1. Ownership by Non-QFPFs

Several comments received in response to the proposed regulations addressed the ownership requirement with respect to QCEs. The proposed regulations did not permit ownership of a QCE by a person other than a QFPF or another QCE, declining to adopt a comment received before the publication of the proposed regulations requesting that de minimis ownership of a QCE by other persons be disregarded under certain circumstances, such as when de minimis ownership by managers or directors is required by corporate law in certain jurisdictions. The Treasury Department and the IRS determined that permitting a person other than a QFPF or another QCE to own an interest in a QCE would impermissibly expand the scope of the exception in section 897(l) by allowing investors other than QFPFs to avoid tax under section 897(a). However, under the proposed regulations, a QFPF could

[1] For consistency with other guidance, the final regulations adopt the term ''foreign jurisdiction'' instead of ''foreign country.'' See § 1.897(l)–1(e)(4). See also Part II.C. of this Summary of Comments and Explanation of Revisions for a description of how the final regulations treat subnational tax regimes.