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 parts 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 § 888.1600 to subpart B to read as follows:

§ 888.1600 Bone indentation device.

(a) *Identification.* A bone indentation device is a device that measures resistance to indentation in bone.

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

(1) In vivo performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate the risk of bone fracture, soft tissue damage, pain, discomfort, bruising, or bleeding.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including an evaluation of the accuracy and precision of the device with respect to resistance to bone indentation.

(3) Human factors testing must demonstrate that the intended user(s) can correctly use the device, based on the instructions for use.

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

(5) Performance testing must demonstrate:

(i) The sterility of the patient-contacting components of the device; and

(ii) Validation of reprocessing instructions for any reusable components of the device.

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

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

(8) Performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(9) Labeling must include:

(i) Instructions for use;

(ii) Validated methods and instructions for reprocessing of any reusable components;

(iii) A shelf life for any sterile components;

(iv) Information regarding limitations of the clinical significance of the device output; and

(v) A detailed summary of the accuracy and precision of the device.

Dated: December 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28601 Filed 1–4–23; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9969]

RIN 1545–BP01

Treatment of Special Enforcement Matters; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations; correction.

SUMMARY: This document contains corrections to final regulations (TD 9969) that was published in the **Federal Register** on December 9, 2022. This correction contains final regulations that except certain partnership-related items from the centralized partnership audit regime created by the Bipartisan Budget Act of 2015, and sets forth alternative rules that will apply to the examination of excepted items by the IRS.

DATES: These corrections are effective on January 5, 2023, and are applicable on December 9, 2022.

FOR FURTHER INFORMATION CONTACT: Concerning the final regulations, Jennifer M. Black, at (202)317–6834 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9969) subject to this correction are under section 6241(11) and 6241(7) of the Internal Revenue Code.

Correction of Publication

Accordingly, the final regulations (TD 9969) that are the subject of FR Doc. 2022–26783, published on December 9, 2022, at 87 FR 75473, are corrected to read as follows:

1. On page 75474, in the second column, the fifteenth line from the top of the first full paragraph, the language ''of partner'' is removed.

2. On page 75474, in the second column, the nineteenth line from the top of the first full paragraph is corrected to read ''additional example of an ineligible partner''.

3. On page 75476, in the first column, the last sentence of the first partial paragraph, the language ''adjustment-year'' is corrected to read ''adjustment year'' wherever it appears.

4. On page 75482, in the third column, the twelfth line from the bottom of the first full paragraph, the language ''partner level'' is corrected to read ''partner-level''.

5. On page 75486, in the first column, in the seventh line from the bottom of the second full paragraph, the language ''easily'' is removed.

6. On page 75486, in the second column, in the third line from the bottom of the second full paragraph, the language ''not'' is removed.

Oluwafunmilayo A. Taylor,

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

[FR Doc. 2022–28594 Filed 1–4–23; 8:45 am]

BILLING CODE 4830–01–P