improper design. FDA believes that manufacturers' adherence to the requirements of the CGMP's would provide reasonable assurance of safety and effectiveness. In light of the new information, FDA believes that the general controls of class I would provide reasonable assurance of safety and effectiveness of the endosseous dental implant accessories for their intended use.

VIII. 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.

IX. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of these devices from class III to class I will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to these devices, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this proposed rule, if issued, will not have a significant ecomomic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XI. Submission of Comments

Interested persons may, on or before January 5, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 in subpart D be amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

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

2. Section 872.3980 is added to subpart D to read as follows:

§ 872.3980 Endosseous dental implant accessories.

(a) *Identification*. Endosseous dental implant accessories are manually powered devices intended to aid in the placement or removal of endosseous implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics and trial abutments. These devices are made from materials currently in use in endosseous implant dentistry.

(b) *Classification*. Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

Dated: September 26, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–26816 Filed 10–6–98; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 53

[REG–246256–94]

RIN 1545–AV60

Failure by Certain Charitable Organizations to Meet Certain Qualification Requirements; Taxes on Excess Benefit Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains a correction to REG–245256–94, which was published in the **Federal Register** on Tuesday, August 4, 1998 (63 FR 41486), relating to the excise taxes on excess benefit transactions.

FOR FURTHER INFORMATION CONTACT: Phyllis D. Haney, (202) 622–4290 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This notice of proposed rulemaking that is the subject of this correction is under section 4958 of the Internal Revenue Code.

Need for Correction

As published, REG–246256–96 contains an error which may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (REG–246256–96), which is the subject of FR Doc. 98–20419, is corrected as follows:

§ 53.4958–4 [Corrected]

On page 41502, column 1, § 53.4958–4(b)(3)(iii), *Example 2*, ninth line from the bottom of the paragraph, the language ''determination of whether N's compensation'' is corrected to read

''determination of whether K's compensation''.

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 98–26920 Filed 10–6–98; 8:45 am]

BILLING CODE 4830–01–M