

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 02N-0114]

DMB

Display Date 5-13-02

Publication Date 5-14-02

Certifier B. LEFSMA

Dental Devices; Reclassification of Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify from class III to class II root-form endosseous dental implants intended to be surgically placed in the bone of the upper or lower arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. FDA is also proposing to reclassify endosseous dental implant abutments, which are separate components that are attached to the implant and intended to aid in prosthetic rehabilitation from class III to class II. This reclassification is being proposed on the Secretary of Health and Human Services (the Secretary's) own initiative based on new information. The agency is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control if this proposal becomes final.

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the Federal Register*]. See section XIII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Angela E. Blackwell, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–8879.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629) and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2)

of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon “new information.” The reclassification can be initiated by FDA or by the petition of an interested person. The term “new information,” as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos v. United States Department of Health, Education, and Welfare*, 587 F.2d at 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 389-91 (D.D.C. 1991)), or in light of changes in “medical science.” (See *Upjohn v. Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the “new information” to support reclassification under section 513(e) of the act must be “valid scientific evidence,” as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc. v. FDA*, 766 F.2d 592

(D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)). FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., nonpublic information in a pending PMA. (See section 520c of the act (21 U.S.C. 360j(c).))

II. Regulatory History of the Device

In the **Federal Register** of August 12, 1987 (52 FR 30082), FDA issued a final rule classifying endosseous implants into class III (21 CFR 872.3640). The preamble to the proposal to classify the device (45 FR 85962, December 30, 1980) included the recommendation of the Dental Devices Panel (the Panel) regarding the classification of the device. The Panel’s recommendation included a summary of the reasons the device should be subject to premarket approval and identified certain risks to health presented by the device. The Panel also recommended under section 513(c)(2)(A) of the act that a high priority for the application of section 515 of the act be assigned to the endosseous dental implant.

In the **Federal Register** of January 6, 1989 (54 FR 550 at 551), FDA issued a notice of intent to initiate proceedings to require premarket approval of 31 preamendments class III devices assigned a high priority by FDA for application of premarket approval requirements. Among other things, the notice described the factors FDA takes into account in establishing priorities for initiating proceedings under section 515(b) of the act for issuing final rules requiring that preamendments class III devices have approved PMAs or declared completed product development protocols (PDP)s. Using those factors, FDA declared that the endosseous implant, identified in 21 CFR 872.3640, had a high priority for initiating a proceeding to require premarket approval. Accordingly, FDA began a rulemaking proceeding to require that endosseous implants have an approved PMA or a PDP that has been declared completed.

In the **Federal Register** of December 7, 1989 (54 FR 50592), FDA issued a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the endosseous implant. In accordance with section 515(b)(2)(A) of the act, the agency summarized its proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet premarket approval requirements, and the benefits to the public from the use of the device. The proposal also provided an opportunity for interested persons to comment on the proposed rule and to request a change in the classification of the device based on new information relevant to its classification. The period for requesting a change in the classification of the device closed on December 22, 1989. The period for commenting on the proposed rule closed on February 5, 1990.

On December 12, 1989, FDA received a petition from the Dental Implant Manufacturers of America (DIMA) requesting a change in the classification of the root-form (i.e., screw, basket, solid and hollow cylinder types) and blade-form endosseous dental implants from class III to class II. The petition was limited to one-stage endosseous implants and the first stage component of the two-stage implant system. The petition's request included implants composed of commercially pure titanium, titanium alloy (Ti-6Al-4V), ceramic single crystal aluminum oxide, and ceramic, polycrystalline alumina. After a number of exchanges between FDA and DIMA to resolve several deficiencies, FDA referred the petition to the Panel for its recommendation on the requested change in classification. The Panel met on October 24, 1991, and voted to deny DIMA's petition (Ref. 1).

Based on information provided by FDA for the October 24, 1991 meeting, the Panel did recommend that screw-type root-form endosseous dental implants be reclassified to class II. The Panel stated that special controls would not be adequate to control some of the risks for other types of endosseous dental implants and recommended that all nonscrew-types remain in class III. In the years following this recommendation, additional clinical data have been reviewed by FDA and the agency believes all root-form endosseous dental implants can be reclassified.

In accordance with section 513(e) of the act and 21 CFR 860.130(b)(2), based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify the root-form endosseous dental implant from class III to class II when intended to be surgically placed in the bone of the upper or lower arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. FDA is further proposing to reclassify endosseous dental implant abutments from class III to class II. Endosseous dental implants, other than root-form, remain in class III and will require the filing of a PMA or PDP at a future date.

The Panel met again on November 4, 1997, with a continuation of the meeting on January 13, 1998. Based on new, publicly available information provided by FDA, the Panel recommended that all root-form endosseous dental implants and endosseous dental implant abutments be reclassified from class III to class II. The Panel believed that class II with special controls would provide reasonable assurance of safety and effectiveness.

III. Device Description

An endosseous dental implant is a device made of titanium or titanium alloy and is uncoated, or coated with titanium or hydroxyapatite, intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Endosseous dental implants are used to attach either removable or fixed prostheses (crowns, bridges, partial removable dentures, or complete removable dentures) and are inserted into either the maxillary or mandibular alveolar ridge.

Endosseous dental implants can be defined as a one-stage or two-stage implant system. These may be loaded after a period of healing or, in some patients for some indications, they may be loaded immediately. Endosseous dental implants can be further generically grouped into four geometrically distinct types: Basket, screw, solid cylinder, and hollow cylinder. These four groups are known as "root-form" implants. Several other geometrical types of implants have been marketed that do not fall within the description of one of these four types and those types are not root-form implants. FDA is proposing to change the classification of only the root-form types.

Endosseous dental implant abutments are premanufactured prosthetic components directly connected to the endosseous implant and are used as an aid for prosthetic rehabilitation.

IV. Proposed Reclassification

Although the Secretary is proposing reclassification on his own initiative, the agency provided new information to the Panel and asked for its recommendation regarding the reclassification of the devices. In a public meeting on January 13, 1998, the Panel unanimously recommended that the root-form endosseous dental implant be reclassified from class III to class II. The Panel believed that class II with a special control guidance document, which includes references to relevant voluntary consensus standards and gives guidance on labeling, would provide reasonable assurance of safety and effectiveness.

The Panel also recommended that endosseous implant abutments be reclassified from class III to class II. They recommended a separate classification from the root-form endosseous implants because the abutments are not considered implants. The Panel believed that class II with a special control guidance document that references relevant voluntary consensus standards would provide reasonable assurance of the safety and effectiveness of the device.

V. Risks to Health

When endosseous dental implants were classified into class III (52 FR 30082, August 12, 1987), the Panel and FDA identified several risks associated with endosseous dental implants for prosthetic attachment, including local soft tissue degeneration, hyperplasia, progressive bone resorption, exfoliation, local and systemic infection (including long term bacterial infection), damage to existing dentition, implant mobility, implant integrity, infectious endocarditis, paresthesia, perforation of the maxillary sinus, and perforation of the labial and lingual alveolar plates. Although the existence of the risks was well documented in numerous books and articles, the rate of occurrence was poorly documented.

Although abutment integrity was not discussed as a specific risk at the 1987 Panel meeting, FDA believes that this risk is a component of implant integrity and, therefore, we have included abutment integrity as a risk associated with endosseous dental implant abutments.

Since the classification of the device, additional data and information became available. Based on a review of the new data and information, the Panel, during an open public meeting on October 24, 1991, identified certain risks (parasthesia, perforation of the maxillary sinus, perforation of the labial and lingual alveolar plates, infectious endocarditis and implant integrity), which had only been addressed for screw type implants by clinical studies. Therefore, they believed that special controls would not adequately address these concerns for all implants. They recommended only the screw type be reclassified into class II (Ref. 1).

At the same meeting, the Panel concluded that the remaining risks of local soft tissue degeneration, hyperplasia, progressive bone resorption, exfoliation, local and systemic infection (including long-term bacterial infection), damage to existing dentition, and implant mobility had been addressed by clinical studies for all types of dental implants.

Although in 1991 the Panel stated that special controls could not adequately address the concern of implant integrity, they also stated that chemical and physical characterization and mechanical testing could partially control this risk with respect to fracture.

When the Panel considered new information, at the November 4, 1997, and January 13, 1998, meetings, they concluded that several published clinical and animal studies (Refs. 4, 5, 6, 7, 8, and 9) showed that the occurrence and incidence of the risks discussed at the 1991 Panel meeting are now well known and are found to be low for all root-form devices and dental implant abutment devices (Refs. 2 and 3).

On the basis of the new clinical studies and the Panel's two recommendations, FDA now believes that the root-form endosseous dental implants and endosseous dental implant abutments do not present a potential unreasonable risk to public health, and that special controls would provide reasonable assurance of the safety and effectiveness of the devices.

VI. Summary of Reasons for Reclassification

After considering the new information and the Panel's recommendations, FDA believes that general controls are not sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA believes that the endosseous dental implants and endosseous dental implant abutments should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the devices, and there is now sufficient information to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Recommendation is Based

In addition to the potential risks to health of endosseous dental implants and endosseous dental implant abutments described in section V of this document, there is reasonable knowledge of the benefits of the device (Refs. 10 and 11). The devices provide increased chewing function and better appearance, resulting in an improved quality of patient life. Based on the available information, FDA believes the special control discussed in section VIII of this document is capable of providing reasonable assurance of the safety and effectiveness of the devices with regard to the identified risks to health of the device.

VIII. Special Controls

In addition to general controls, FDA believes that the guidance document entitled "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA" is an adequate special control to address the potential risks to health described for the root-form endosseous dental implants and endosseous dental implant abutments.

The guidance document would indicate when clinical data are appropriate and what engineering testing is needed. It will reference voluntary consensus standards that are relevant for these devices. It also will provide device specific labeling guidance. FDA believes that adherence

to the guidance document would control implant and abutment fracture by providing guidance and reference to methodologies for chemical and physical characterization and mechanical testing.

To receive a copy of “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA” via fax machine, call CDRH Facts-on-Demand system at 800–899–0381, or 301–827–0111 from a touch-tone telephone. Press 1 to access the system. At the second voice prompt, press 2, and then enter the document number (1389) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. The draft guidance is also available on the Internet and may be accessed at <http://www.fda.gov/cdrh> and at <http://www.fda.gov/ohrms/dockets/defaults.htm>.

IX. FDA’s Tentative Findings

FDA believes the root-form endosseous dental implants and endosseous dental implant abutments should be classified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

X. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed reclassification 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.

XI. 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 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 II will relieve all manufacturers of these devices of the cost of complying with premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory cost 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 reclassification action, as issued, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action 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 or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

XII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information.

XIII. Submission of Comments and Proposed Dates

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this proposal by [*insert date 90 days after date of publication in the Federal Register*]. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

XIV. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Transcript of the Dental Products Panel Meeting, October 24, 1991.
2. Transcript of the Dental Products Panel Meeting, November 4, 1997.
3. Transcript of the Dental Products Panel Meeting, January 13, 1998.
4. Buser, D., et al., "Influence of Surface Characteristics on Bone Integration of Titanium Implants. A Histomorphometric Study in Miniature Pigs," *Journal of Biomedical Materials Research*, vol. 25, pp. 889–902, 1991.
5. Carr, A. B., et al., "Reverse Torque Failure of Screw-shaped Implants in Baboons: Baseline Data for Abutment Torque Application," *International Journal of Oral and Maxillofacial Implants*, vol. 10, pp. 167–174, 1995.
6. Adell, R., et al., "A Long-term Follow-up Study of Osseointegrated Implants in the Treatment of Totally Edentulous Jaws," *International Journal of Oral and Maxillofacial Implants*, vol. 5, pp. 347–359, 1990.
7. O’Roark, W. L., "Research Report: Improving Implant Survival Rates by Using a New Method of at Risk Analysis," *International Journal of Oral Implantology*, vol. 8, No. 1, pp. 31–57, 1991.
8. Buser, D., et al., "Long Term Evaluation of Nonsubmerged ITI Implants. Part 1: 8-year Life Table Analysis of a Prospective Multi-center Study With 2359 Implants," *Clinical Oral Implants Research*, vol. 8, pp. 161–172, 1997.

9. Block, M. S., J. N. Kent, "Cylindrical HA-coated Implants—8-year Observations," *Compendium of Continuing Education Dentistry*, Supplement 15, pp. 526–532, 1993.

10. Proceedings of the 1996 World Workshop in Perisontics, *Annals of Periodontology*, vol. 1, No. 1, pp. 707–820, 1996.

11. Misch, C. E., *Contemporary Implant Dentistry*, St. Louis, MO: Mosby, pp. 89–118, 1999.

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 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 872.3630 is added to subpart D to read as follows:

§ 872.3630 Endosseous dental implant abutment.

(a) *Identification.* An endosseous dental implant abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid for prosthetic rehabilitation.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Final Guidance for Industry and FDA."

3. Section 872.3640 is revised in subpart D to read as follows:

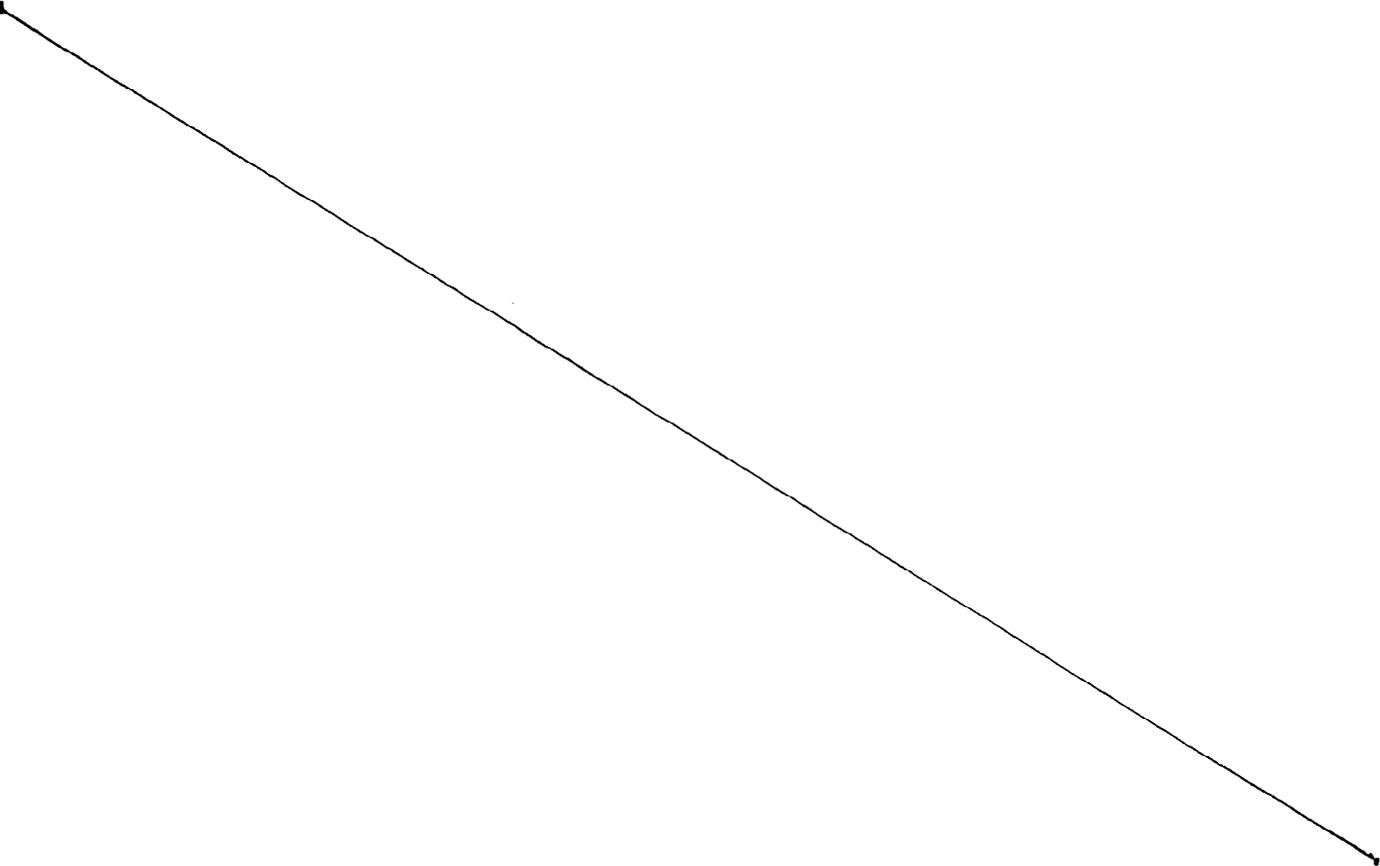
§ 872.3640 Endosseous dental implant.

(a) *Identification.* An endosseous dental implant is a device made of a material such as titanium or titanium alloy intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

(b) *Classification.* (1) Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Final Guidance for Industry and FDA."

(2) Class III for endosseous dental implants other than the root-form.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established for the requirement for premarket approval for the devices described in paragraph (b)(2) of this section. See § 872.3 for the effective dates of requirement for premarket approval.



Dated: 4/23/02
April 23, 2002.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. ⁰²00-????? Filed ⁰²??-??-00; 8:45 am]

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Regina Sedeno