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September 6, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20862

RE: Docket No. 02N-0114

Below are our comments on the proposed rule and guidance document in accordance with XIII of Federal Register Docket No. 02N-0114 (May 14, 2002).

1. We agree that root-form endosseous dental implants, as well as, endosseous dental implant abutments, should be classified into Class II, special controls.
2. Will the final document also supersede the *510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants* guideline?
3. In order to ensure a clear medical and technical terminology, we believe that the term "fixture" should be replaced by "endosseous implant" throughout the document.
4. We believe that related accessories should be addressed in the Identification of the abutment. This would include fastening screws, impression caps, etc. We recommend that §872.3630 be revised to include the accessories, i.e., "Endosseous Dental Implant Abutment and Accessories".
5. In accordance with Item 3 above, to include the abutment accessories when referencing the endosseous dental implant abutment throughout the guidance document, the following sentence should be amended on Page 1 of the guidance document: "The endosseous dental implant abutment device, with accessories, is intended to be used with the endosseous implant to aid in prosthetic rehabilitation."
6. a. In the Intended Use of the Device section of the guidance [under Abbreviated 510(k) Content, Page 4], the first sentence should be amended by adding "if applicable" at the end of the sentence. **02N-0114** **C2**
b. If a manufacturer does not intend their implants to be used with the implant abutments or accessories of other manufacturers, there should be no requirement that compatibility information be included in the 510(k).

Dockets Management Branch (HFA-305)
September 6, 2002
Page Two

7. a. In the first paragraph of the Fatigue Testing in Compression and Shear section of the guidance (Page 8), all devices should undergo mechanical testing, not just those categories of devices listed here.
 - b. With reference to the Fatigue Testing in Compression and Shear section of the guidance on Page 9, a separate test setup is identified for angled abutments. This special setup test for angled abutments is not necessary. When using the standardized test setup in ISO/DIS 14801.2 (a 30° loading angle), implant abutment connection strength can be tested for angled abutments since the abutment-implant connection is identical.
8. a. In the Ceramic Coating Information section (under Modified Surfaces Information, Page 10) of the guidance, "**for the coating**" should be added to the requirement for "average porosity size".
 - b. Again, in the Ceramic Coating Information section (under Modified Surfaces Information, Page 10) of the guidance, "**for the coating**" should be added to the requirement for "overall pore volume".
8. a. In the Metallic Coating Information section (under Modified Surfaces Information, Page 11) of the guidance, the first requirement should read "complete chemical composition of the **powder used for coating and of the coating itself**".
 - b. In the Metallic Coating Information section (under Modified Surfaces Information, Page 11) of the guidance, the requirement is for the "mean volume percent of voids". What are the specific requirements for this measurement and the method to be used?

If you have any questions regarding these recommendations or which to discuss any of the above items, please contact me.

Regards,



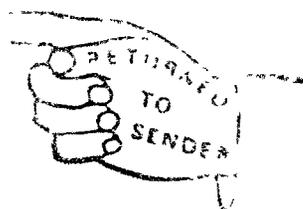
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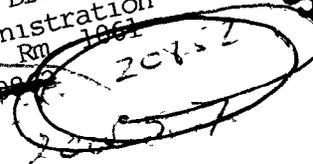


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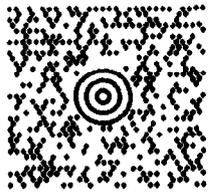


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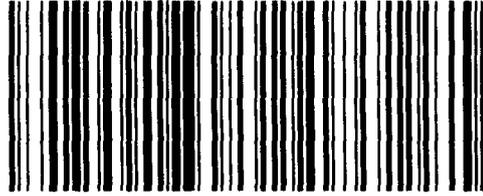
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