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DENTAL IMPLANTS



November 12, 2002

Food and Drug Administration
Center for Devices and Radiological Health
Regulations Staff (HFZ-215)
1350 Piccard Drive
Rockville, MD 20857

RE: Reclassification Petition-Beta-Tricalcium Phosphate

Dear Sir/Madam:

The enclosed documents are a Petition for Reclassification of Beta-Tricalcium Phosphate, and devices found equivalent to it, from Class III to Class Unclassified.

The petition is being submitted under Sections 513(e) and (f), 514(b), 515(b) and 520(l) of the act which allows for reclassification of a device and outlines the procedures to be followed. The information presented is submitted according to the reclassification procedure 21 CFR 860.123.

Your prompt attention to this submission is very much appreciated. Please contact me with any questions you may have.

Sincerely,

Vincent J. Morgan, D.M.D.
President

02P-0520

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