

APPENDIX A

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Regulatory Status of CAD/CAM Systems for Dental Restorations



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OEC - 5 1988

Food and Drug Administration  
8757 Georgia Avenue  
Silver Spring MD 20910

Dentsply International  
Attn: John O. Semmelman, Corporate Director  
Product Compliance  
570 West College Avenue  
P.O. Box 872  
York, Pennsylvania 17405-0872

Re: K884166  
Dicor Ceramic Inlay - New Technic  
Dated: October 1, 1988  
Received: October 4, 1988

Dear Mr. Semmelman:

Thank you for your recent letter informing us of the new technology you intend to employ in the dental ceramic inlay production process. While FDA agrees that the CAD/CAM system is not regulated, we do feel that a 510(k) is required for the powder which is applied to the tooth to enhance the image and the camera used to record the topographical characteristics of the tooth. In this light, the following additional information letter has been compiled.

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require results of clinical trials demonstrating the equivalence of the Dicor Ceramic New Technic to previously marketed devices. This technical data would show that the resultant topographic information is as effective as impression material for use in production of dental inlays. This data must also show that there is no impact on safety as a result of this new technology.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until 90 days after you have provided adequate information described above and required by 21 CFR 807.87(f) and (h). If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

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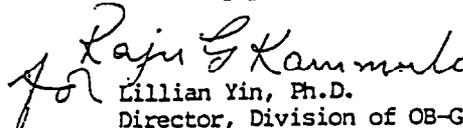
The requested information should reference your above 510(k) number and should be submitted to:

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ-401)  
8757 Georgia Avenue  
Silver Spring, Maryland 20910

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Mrs. Monica Ferrante at (301) 427-8185. If you have general questions regarding 510(k) procedures or policies, you may contact Mr. Robert I. Chissler at (301) 427-8162. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

  
Lillian Yin, Ph.D.  
Director, Division of OB-GYN, ENT and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health