DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Ombudsman
5600 Fishers Lane (HF-7)
Room 14B-03
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

January 11, 2000

P. Jeffery Lehn
Director, Corporate Compliance
and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872

Re: Request for Designation[1]
Nupro® Prophy Paste with Fluoride and Triclosan
Our File: RFD 99.015

Dear Mr. Lehn:

We have completed our review of your request for a product jurisdiction determination, received and filed on November 12, 1999.

Nupro® Prophy Paste with Fluoride and Triclosan (the "product") is a dental prophylactic paste. The product's formulation is described in detail in the request and is incorporated here by reference. The product was the subject of a request for designation in 1998. The initial RFD was for the product when indicated for "cleaning and polishing procedures as part of a professionally administered prophylaxis treatment." In a letter dated June 11, 1998, this office classified the product as a medical device and assigned premarket review responsibility to the Center for Devices and Radiological Health (CDRH). The 1998 designation letter limited the jurisdictional decision to the use of the product for cleaning and polishing teeth during professional prophylaxis treatment. Dentsply is currently marketing Nupro® Prophy Paste with Fluoride and Triclosan for this indication under a 510(k) premarket notification (k983966).

In Dentsply's new request for designation, the company seeks to add to the label of the marketed product an indication for "professional cleaning and polishing of plastic oral appliances and prostheses, which have been removed from the mouth."

The request for designation seeks guidance on how the agency will classify and assign the product for its new use. The request recommends that the product when intended for the new indication still be classified as a medical device, and that premarket review responsibility remain with the Center for Devices and Radiological Health

[1] 21 CFR Part 3

(CDRH). Dentsply argued that its recommendation is supported by the Intercenter Agreement between the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH), which in section VIII.A.5. assigns CDRH responsibility for review of a device containing a drug substance as a component with the primary purpose of the combination being to fulfill a device function.

After considering the information in the designation request, and consulting with appropriate officials in CDER and CDRH, we agree with Dentsply's recommendations. Therefore, CDRH is assigned primary responsibility for the premarket review and regulation of the product. The product will be reviewed under the medical device provisions of the Federal Food, Drug, and Cosmetic Act.[2] Our decision is based on the view that the primary mode of action of this combination product for the new intended use is attributable to its physical and chemical properties as an ex vivo cleaning and polishing agent. As noted in the request for designation, the assignment to CDRH is consistent with the guidance of the CDER-CDRH Intercenter Agreement, which assigns CDRH responsibility for devices with a drug component whose primary intended purpose is to fulfill a device function. See sections VII.(b)2. and VIII.A.5.

The Division of Dental, Infection Control, and General Hospital Devices in the Office of Device Evaluation, CDRH, will be the primary review group. The Division will conduct its review in consultation with CDER staff, as appropriate. For further information, contact Dr. Susan Runner, Branch Chief, Dental Devices Branch, Division of Dental, Infection Control, and General Hospital Devices, Office of Device Evaluation, CDRH, 9200 Corporate Boulevard (HFZ-480), Rockville, MD 20850, or by telephone at 301-443-8879. Please include a copy of this letter in your initial submissions to CDRH.

If you have any questions about this designation decision, please contact me at 301-827-3390.

Sincerely yours,

Steven H. Unger
Acting Ombudsman

cc: Dr. Runner

[2] 21 U.S.C. § 360c et seq.