DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Chief Mediator and Ombudsman
5600 Fishers Lane
Room 14-105
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

June 11, 1998

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
Nupro® Prophy Paste with Fluoride and Triclosan
Our File: RFD 98.008

Dear Mr. Lehn:

We have completed our review of your request for a product jurisdiction determination, received by this office on April 16, 1998, and filed April 17, 1998.

Nupro® Prophy Paste with Fluoride and Triclosan (the "product") is a dental prophylactic paste. The product's formulation is described in detail in your request, and that description is incorporated here by reference. Dentsply is currently marketing a prophylactic paste - Nupro® Prophy Paste with Fluoride - under a 510(k) premarket notification (k912945). Nupro® Prophy Paste with Fluoride and Triclosan contains [redacted] Triclosan, but is otherwise identical in formulation to the previously cleared prophylactic paste.

According to the request for designation, the product will be indicated for the same uses as Nupro® Prophy Paste with Fluoride, i.e., to be used for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment. Although the product contains an antimicrobial ingredient, Triclosan, "[N]o claims for prolonged or sustained antimicrobial efficacy will be made."

Dentsply recommended that the product be regulated as a medical device, and that premarket review responsibility be assigned to the Center for Devices and Radiological Health (CDRH). Dentsply suggested that its recommendation was 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 substantially 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. 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.

Please note that the designation decision applies solely to the product when indicated for use for cleaning and polishing teeth as part of a professionally administered prophylaxis treatment. Should Dentsply decide to make any claims of antimicrobial efficacy for the product, a separate request for designation should be submitted.

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

Sincerely yours,

Steven H. Unger
Deputy, Office of the Chief Mediator and Ombudsman

cc: Dr. Runner