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

May 9, 2000

Dean A. Knight
Manager, Cardiovascular Regulatory Affairs
Cordis
40 Technology Drive
Warren, NJ 07059

Re: Request for Designation (21 CFR Part 3)
Sirolimus-Coated BX VELOCITY™ Balloon-Expandable Stent with Raptor Delivery System
Our file: RFD 0.006

Dear Mr. Knight:

The Food and Drug Administration has completed its review of Cordis' request for designation, filed by this office on April 3, 2000. Cordis supplemented its original request by facsimile dated May 5, 2000.

Cordis requested jurisdictional classification and assignment of its Sirolimus-Coated BX VELOCITY™ Balloon-Expandable Stent (Cordis stent) with Raptor Delivery System. The stent is implanted during balloon angioplasty using Cordis' Raptor Delivery System.

The Cordis stent is indicated for use in "improving coronary luminal diameter in patients with symptomatic ischemic disease due to discrete lesions in *de novo* [ ] [ ] (Request at 6) The stent is a sirolimus coated stainless steel tube intended to be permanently implanted in coronary arteries to open the vessel "by providing a mechanical buttress that resists mechanical compression." (Request at 6) Sirolimus is currently marketed for the prophylaxis of organ rejection in patients receiving renal transplants. Sirolimus will be coated on the stent "to serve the ancillary purpose of retarding formation of intimal hyperplasia." (Supplemental information at 2)

Cordis, while acknowledging that consultation with FDA's Center for Drug Evaluation and Research (CDER) may be necessary, recommended that the Center for Devices and Radiological Health (CDRH) have primary jurisdiction over the product because the combination product's primary function is to improve "coronary luminal diameter by a purely mechanical means, i.e. by buttressing or providing scaffolding to the vessel wall." (Supplemental information at 2)

We have considered the information in the request, reviewed the pertinent provisions of the ICA, and discussed the issues raised with staff in the two centers. Because the Cordis stent is a combination product within the meaning of section 503(g) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 353(g)), review responsibility is assigned based on the agency's determination of the product's "primary mode of action." We note that the primary purpose of the combination product is to physically buttress the vessel wall -- a device function -- and that sirolimus is present to augment the product's safety and efficacy. Therefore, we conclude that the primary mode of action of the product is that of the device component and that CDRH should be assigned principal review responsibility. This jurisdictional decision is consistent with sections VII.A.2 and VIII.A.5 of the ICA, which assign CDRH review responsibility for any device incorporating a drug component with the combination product having the primary intended purpose of fulfilling a device function.

The Cordis stent will be subject to review and approval under the medical device provisions of the Act. (See 21 U.S.C. § 360c *et seq.*) Moreover, we have been advised that the product will be subject to the premarket approval application (PMA) requirements.

The Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND) in the Office of Device Evaluation, CDRH, will be the primary review group. The Division will conduct its review in consultation with CDER. For further information, contact Christopher Sloan, Branch Chief, Interventional Cardiology Group, DCRND, Office of Device Evaluation, CDRH, 9200 Corporate Boulevard, (HFZ-452), Rockville, MD 20850, or by telephone at 301-443-8243.

Please note that the designation decision applies solely to the combination product when promoted for use as a coronary stent. Any other proposed use of the combination product or sirolimus would require separate jurisdictional guidance.

If you have any questions concerning this matter, please contact Tracey Forfa, of this office, at 301-827-3390.

Sincerely yours,

Steven H. Unger
Acting Ombudsman

cc: C. Sloan