Novoste™
3890 Steve Reynolds Boulevard
Norcross, GA 30093
Tel: 770.717.0904 Fax: 770.717.1283

March 26, 2002

Mr. Eric Jameson
Radioactive Materials Program
Environmental Protection Division
State of Georgia, Department of Natural Resources
4244 International Parkway, Suite 114
Atlanta, Georgia 30354

RE: FDA approval of the Novoste™ Beta-Cath™ System Model A1730.

Dear Mr. Jameson:

As anticipated by the FDA during the recent conference call between yourself, Mr. Reed and Mr. Heaton, Novoste has just received approval to market the Novoste™ Beta-Cath™ System, Model A1730 consisting of a 60 mm radiation source train. Attached is a copy of the approval letter received by FDA dated March 25, 2002. As you can imagine, our customers are looking forward to providing a treatment so beneficial to patients with longer lesions. Such patients, unfortunately, suffer the most due to the complexity of their disease.

Please amend our radioactive materials license GA 1350-2 to authorize distribution of the Beta Cath System, model A1730. Also, please update the Sealed Source and Device Registration certificate GA-1115-D-101-S to reflect FDA approval of Model A1730.

I will follow up via telephone to determine the time line for completion. **Please note, we intend to begin distribution to sites within three weeks.** As you can imagine, we are looking forward to providing a product so useful for the treatment of so many patients.

If you have questions on this matter please contact myself or Mr. Craig Reed, Director, Regulatory Affairs. Once again, we appreciate your thorough and prompt service.

Sincerely,

Robert Cooper, CHP
Senior Scientist
Regulatory Affairs

cc: Craig Reed, Director
Andrew Green, Director
Mr. Tom Hill

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2002

Mr. Andrew M. Green
Director, Regulatory Affairs
Novoste Corp.
3890 Steve Reynolds Blvd.
Norcross, GA 30093

Re: P000018/S18
Novoste™ Beta-Cath™ 3.5 Fr System
Filed: August 30, 2001
Amended: September 10, 2001, November 13, 2001, January 24, 2002, and March 4, 14, 18, 2002

Dear Mr. Green:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for the Novoste™ Beta-Cath™ 60 mm 5 Fr System. The Novoste™ Beta-Cath™ 60 mm 5 Fr System is intended to deliver beta radiation to the site of successful percutaneous coronary intervention (PCI) for the treatment of in-stent restenosis in native coronary arteries with discrete lesions with injury areas up to 40mm in a reference vessel diameter ranging from 2.7mm to 4.0mm. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements outlined in the enclosure, you have agreed to provide the following data in a postapproval report:

> Although the RENO-Long clinical data provide reasonable assurance of the safety and effectiveness of the 60 mm 5 Fr Beta-Cath System, FDA believes that a post-approval study is necessary to further validate the clinical performance of the system and assess the long-term safety of the radiation treatment. FDA acknowledges that you have provided a preliminary outline for this study protocol and that the data should be gathered in accordance with the outline of the study protocol provided in Amendment 5 to this Supplement. A more detailed protocol for this investigation should be provided to FDA for review. Please be advised that a summary of this investigation should be incorporated into the labeling when the study results are available.

Expiration dating for the β-Cath 60 mm 5 Fr Delivery Catheter and Procedure Pack components has been established and approved at 2 years. Expiration dating for the Transfer Device and Source Train components has been established and approved at 6 months or 125 uses.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

You are reminded that as soon as possible and before commercial distribution of your device you must submit an amendment to this PMA with copies of all approved labeling in final form. The labeling will not routinely be reviewed by FDA staff when PMA supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Kimberly Bowie Peters at (301) 443-8243.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure