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

February 12, 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™ 3.5F System.

Dear Mr. Jameson:

Novoste has just received approval to market the Novoste™ Beta-Cath™ 3.5F System consisting of the Model A1767 Transfer Device and the AEAT Model SICW.2 jacketed source train for the approved 30mm and 40mm sources trains. Attached is a copy of the approval letter received by FDA dated February 8, 2002.

Please amend our radioactive materials license GA 1350-2 to authorize distribution of the Beta Cath System, model A1767 as described in recent correspondence from Mr. Reed.

Also, please remove Phil Brown from our GA-1350-2 license as an authorized user.

We look forward to recieving the updated registration certficate to reflect the A1767 Transfer Device with up to 24 AEAT Model SICW.2 jacketd sources in 60mm trains as well as the new Corona System. Please note that those devices are being placed into use for clinical research in accordance with FDA requirements as well as physics/calibration purposes and a safety evaluation is necessary for licensing purposes.

If you have questions on this matter please contact me or Mr. Craig Reed, Director, Regulatory Affairs.

Sincerely,

Robert Cooper, CHP
Senior Scientist
Regulatory Affairs

cc: Craig Reed, Director
John Lobdell, Ph.D., RSO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2002

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

Re: P000018/S15
Novoste™ Beta-Cath™ 3.5 Fr System
Filed: July 31, 2001
Amended: September 10, 2001, January 7, 22, and 29, 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™ 3.5 Fr System. The Novoste™ Beta-Cath™ 3.5 Fr System is indicated 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 (treatable with a 20 mm balloon) in a reference vessel diameter ranging from 2.7 mm to 4.0 mm. 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 Euro-START 40 clinical data, and the comparative dosimetry information to the 5 Fr Beta-Cath System provide reasonable assurance of the safety and effectiveness of the 3.5 Fr Beta-Cath System, FDA believes that additional prospective clinical data should be obtained with the system to further validate that the clinical performance of the 3.5 Fr Beta-Cath System is comparable to that of the 5 Fr Beta-Cath System, and to assess the long-term safety of the radiation treatment. These data should be gathered in accordance with the outline of the study protocol provided in your January 4, 2002, submission. 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-Rail 3.5 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