

# **Georgia Department of Natural Resources**

4244 International Parkway, Suite 114, Atlanta, Georgia 30354

Lonice C. Barrett, Commissioner

Environmental Protection Division

Harold F. Reheis, Director

(404) 362-2675

August 4, 2000

Ms. Joan McDonald, Ph.D.  
Vice President, Regulatory Affairs  
Novoste Corporation  
3890 Steve Reynolds Boulevard  
Norcross, GA 30093

Dear Ms. McDonald:

Enclosed is a copy of the new "Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Device" Number GA-1115-D-101-S, Beta-Cath System Intravascular Brachytherapy Device, per your request dated June 30, 1999. A copy of the registration certificate has been forwarded to the United States Nuclear Regulatory Commission for inclusion in the sealed source and device registry.

Please note that even though the device evaluation has been issued, it is still only authorized for clinical trials. Authorization for general medical use will require PMA from the FDA, as well as our program issuing Novoste a distribution license.

Information to support the distribution license was submitted with the application for device evaluation. Final review will be performed upon receipt of the PMA.

If you should have any questions, please call our office at (404) 362-2675.

Sincerely,



Eric T. Jameson  
Environmental Radiation Specialist  
Radioactive Materials Program

Enclosure