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January 22, 2002

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

RE: FDA Status Regarding Update to Beta-Cath™ System Registration GA-1115-D-101-S (RAML GA 1350-2)

Dear Mr. Jameson:

The purpose of this letter is to communicate the FDA status of Novoste intravascular brachytherapy devices submitted to the Department for registration. We have not received any requests for additional information regarding the devices and we want to ensure that the Department has the necessary information to make an updated registration certificate available to other licensing authorities for devices currently in their jurisdiction and to permit licensing of our expanded distribution authority. Table 1 lists devices and sources that are either scoped by an FDA Pre-market Approval (PMA), an FDA investigational Device Exemption (IDE) or are in the process of being submitted to the FDA for approval/clearance which we would like to discuss.

Table 1.

Device, Source	New or Updated Registration Request date	FDA Status	In Use?
A1732, Sr0.S03	2/26/01	Approved for Marketing	Yes
A1733, Sr0.S03	2/26/01	Approved for Marketing	Yes
A1730, Sr0.S03	2/26/01	Active IDE, **Pre-Market Approval expected Feb 2002**	Yes
A1767, SICW.2	4/9/01	Active IDE, **Pre-Market Approval expected Jan 2002**	Yes
GTA-0050, GTA-0035, A1760 and SICW.1	4/9/01	Submission in Progress	No, possibly by 3Q2002

The Model A1730 with Sr0.S03 sources and the Model A1767 with SICW.2 sources are approved for medical research use via IDE's. The FDA Pre-Market Approvals for these devices are expected within the month. Licensees, license reviewers and inspectors outside Georgia would benefit from an updated certificate describing the devices.

Important Distinctions and Clarifications Between Systems

The A1000 Series devices are the Transfer Device components of all Novoste intravascular brachytherapy devices, including Beta-Cath™ and Corona Systems.

The **Beta-Cath™ (5Fr) System** is the Model A1732, A1733 or A1730 device containing Sr0.S03 sources attached to a 5 French (5/3mm diameter), three-lumen Delivery Catheter approved for use in small lumens, e.g., the coronary arteries.

- The range of sources activities approved for use in the coronary arteries is 2.7 to 4.0 mCi.
- Casually referred to as the "5 French System"
- Model A1732 and A1733 devices with 30mm and 40mm source trains, repectively, are approved by the FDA. **Approval for the A1730 with the 60mm source train is expected in February 2002.**

The **Beta-Cath™ 3.5 Fr System** is the Model A1767 device with *jacketed* SICW.2 sources attached to a 3.5 French, coaxial, two-lumen Delivery Catheter designed for use in small lumens, e.g., the coronary arteries.

- FDA approval is expected January 2002
- Each train is calibrated for dose rate using a NIST traceable standard train. Activity values will be obtained from the vendor, AEAT, until NIST can provide Novoste with a standard for activity calibrations.
- The dose rate and activity range of the 3.5Fr System will be equivalent to the 5Fr System.
- The 3.5 Fr System is scoped under an FDA IDE and is being transferred to hospitals that are licensed for research.
- The 3.5 Fr System Delivery Catheter is manufactured with a removable wire tool inserted into the source train lumen. The wire provides support to the catheter lumens during handling and placement in the patient and is configured with radiopaque markers that simulate the physical properties of the jacketed radiation source train. The wire is removed after the catheter is placed inside the patient and before the device is connected to the catheter. Removal of the wire allows the user to check navigability of the source train lumen – if the lumens are patent, the wire should be easy to remove. **The wire replaces the Dummy Run recommended for the 5Fr System.**

The "**Corona™ System**" is the Model A1730 device containing Sr0.S03 sources attached to a four-lumen, balloon equipped Delivery Catheter for use in larger vessels, e.g., the peripheral arteries outside the heart.

- The Corona System is currently being transferred to hospitals under an IDE for use in the MOBILE Clinical Trial to study the treatment of instent restenosis of superficial femoral and popliteal (leg) arteries.
- Range of sources activities to be used in the MOBILE trial is 2.7 to **5.0** mCi.

- A hemostasis valve (e.g., Touhy-Borst valve) is not used in peripheral interventions, that mechanism is not present for user's to crimpt the catheter and accordingly, **there is no need to evaluate use of a protective introducer sheath.**

- **A Dummy Run is not recommended** because the Corona Catheter is a large, robust catheter with lumens that are not likely to be challenged by handling or placement in the peripheral arteries which are relatively straight in comparison to coronary arteries.

Also, in order to simplify licensing of our products and for consistency with existing rules, we intend to recommend that licensees seek the following license conditions to scope all products:

Isotope: Sr-90

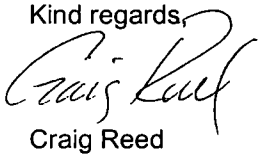
Form: Sealed Sources (BEBIG Sr0.S03, AEAT SICW.2)

Quantity: 5 mCi maximum per source; 500 mCi total;

Authorized Use: For use in Novoste A1000 Series devices for intravascular brachytherapy.

We are interested in hearing your comments to the recommended licensing language and would like discuss the Department's timeline for updating the Beta-Cath™ System registration certificate. Again, please contact us upon your review of this letter so that we may arrange a meeting to answer questions or resolve concerns as necessary for issuance of a revised registration certificate. If you have any questions, please do not hesitate to contact me or my associate, Bob Cooper, CHP at (770) 717 0904.

Kind regards,



Craig Reed
Director, Regulatory Affairs
Novoste