Eric Jameson - RE: items to finish BetaCath review

From: "Reed, Craig" <CReed@novoste.com>
To: Eric Jameson <EJameson@mail.dnr.state.ga.us>
Date: 02/21/2002 19:29
Subject: RE: items to finish BetaCath review
CC: Tom Hill <THill@mail.dnr.state.ga.us>

Eric,

The unredacted confidential drawings and reports are ready and answers to your questions are included below. I'll contact you in the morning for the schedule.

Kind regards,

Craig

-----Original Message-----
From: Eric Jameson [mailto:EJameson@mail.dnr.state.ga.us]
Sent: Thursday, February 21, 2002 5:10 PM
To: creed@novoste.com; rcooper@novoste.com
Cc: Tom Hill
Subject: items to finish BetaCath review

As mentioned in an email earlier this week, I would like to have copies of some of the confidential documents referenced in Novoste's submittals for the BetaCath SS&D amendment. These documents would be returned upon issuance of the revised SS&D registry certificate.

Considering the late hour today, I would be willing to pick up the documents from your office tomorrow morning rather than have them over-nighted, as this will save on time.

The confidential documents that I would like copies of are as follows:

drawings of AEA SICW.1 and SICW.2n sealed sources;
drawings of the 3.5Fr and Corona catheters and connectors;
drawings of GTA-0050 and GTA-0035 guide tubes;
drawing of quartz shield for A1767;
AEA design report DSGN-0281;
Cycle Test Studies RD-540-017 and RD-540-028.

Also, as I finished reviewing the last items of correspondence, I came up with the following questions, most of which just require confirmation from Novoste.

1) Do the design changes to the Transfer Device to make the counter, 2nd battery, etc. optional features require FDA approval or review? *** Yes. The FDA review period is 30 days for inclusion of the change into an investigational clinical device (IDE) and 180 days for inclusion in a commerical device (PMA). It's also beneficial to describe the optional configurations in the SS&D certificate because user's outside the U.S. will see the changes likely before any FDA approvals.

2) Regarding the replacement of batteries by users: Have there been any

maintenance issues/needs noticed by by Novoste or the FDA at the period cycle exchange intervals? **** No and we're not proposing any change to the six month service interval. We're anticipating that multiple dwell positions required to treat long lesions in the peripheral arteries currently under investigation per FDA IDE in the MOBILE Clincal Trial will exhaust the single battery in the A1730 before six months elapses. We would still exchange the device for service at the the recommended interval even if they replace the battery. ***

3) Will the batteries be "off-the-shelf" (i.e., 9V, C-cell, AAA) or custom-supplied from Novoste/its vendors? *** Off the shelf.***

4) Confirm that the AEA SICW.1 sealed source has not received FDA approval for use in the BetaCath. ***Confirmed. We would have to obtain FDA approval as a PMA supplement with a review period of up to 180 days.***

5) In letter dated 1/22/02, page 2 refers to the Corona System as Model A1730. Please confirm that Corona System is Model A1760, as in previous submittals. ****The Corona System Transfer Device is the Model A1730, same as the Beta-Cath System Transfer Device with the 60mm Radiation Source Train. We just received an "approvable letter" from the FDA for the Beta-Cath System with the Model A1730 Transfer Device. All we have to do for full approval is to answer a couple of questions that the FDA indicated we had already answered, but in a separate filing. They need us to confimr that those answers apply to the 60mm device and I understand that they do.***

I will be in the office by 8:00am tomorrow. Please contact me after that time to coordinate document pick up and also if you have any questions about this transmittal.

Sincerely,

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