

From: Seung Lee
To: Inet: rflanagan@DRAXIMAGE.com
Date: Tue, May 16, 2000 10:16 AM
Subject: Request for Additional Information for Model LS-1 Brachytherapy Source

Good morning, Dr. Flanagan!

I received your respond last week. However, some more information are needed to complete your application:

1. Please provide FDA 510(k) certification.
2. In your Application and Review Checklist, both specific and general licensees is checked. Do you want the Model LS-1 to be generally licensed source? If so, there are so many information missing in your application, we have to reject your application. Please confirm your intention for Model LS-1 use.
3. ISO 9978-1992 requires the brachytherapy sources be leak tested by the immersion test. Please provide the comparison between your proposed method and ISO 9978 method.

Please respond within 30 days of the date of this e-mail. If we have not received the requested information within 30 days, we will assume that you have abandoned your application. This assumption is, however, without prejudice and you may resubmit a complete application after that time.

If you have any questions, please contact me at (301) 415-5787 (W), (301) 415-5369 (fax), or send me an e-mail to sjl@nrc.gov.

Thank you very much and have a nice day.

Seung

CC: JPJ2

Mail Envelope Properties

(39215834.506 : 6 : 20584)

Subject: Request for Additional Information for Model LS-1 Brachytherapy Source
Creation Date: Tue, May 16, 2000 10:16 AM
From: Seung Lee

Created By: TWFN_DO.TWF4_PO:SJL

Recipients	Action	Date & Time
Post Office Inet rflanagan (Inet: rflanagan@DRAXIMAGE.com)	Transferred	05/16 10:16 AM
Post Office TWFN_DO.twf4_po	Delivered	05/16 10:16 AM

JPJ2 CC (JPJ2)

Opened

05/16 10:56 AM

Domain.Post Office

Inet
TWFN_DO.twf4_po

Delivered

05/16 10:16 AM

Route

Inet:DRAXIMAGE.com
TWFN_DO.twf4_po

Files

MESSAGE

Size

2125

Date & Time

Tuesday, May 16, 2000 10:16 AM

Options

Auto Delete: No
Expiration Date: None
Notify Recipients: Yes
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard

To Be Delivered: Immediate
Status Tracking: Delivered & Opened