June 16, 1998

Walter W. Davis, Jr.
Assistant Dean and
Chief Facilities Officer
Washington University and Medical Center
P.O. Box 8053
660 South Euclid Avenue
St. Louis, MO 63110-1093

SUBJECT: NRC INSPECTION REPORT DATED APRIL 21, 1998

Dear Mr. Davis:

This acknowledges receipt of Drs. Perez and Siegel's letter dated May 18, 1998, in response to our April 21, 1998, letter transmitting Inspection Report 030-02271/98001(DNMS). In that report we raised a concern for safety evaluations completed by your Radiation Safety Committee (RSC) for unreviewed medical devices.

Your staff's May 18, 1998, letter indicated that you are concerned about NRC placing the burden for a safety evaluation on the RSC after the Federal Drug Administration (FDA) has already completed a review and approved the device for clinical trial use. Further, you believe the RSC was not responsible for making inquiries of the sponsor about safety issues that the sponsor may not have previously reported to the FDA. Finally, you believe the mechanism for reporting significant device failures, from the past and any new device incidents, currently exists with the FDA so that the RSC's reliance on the FDA approval of the clinical trial was sufficient to ensure that the device was designed safely and that instructions for safe use were adequate.

The NRC is continuing its review of your response and will contact you upon completion of our review.

If our understanding differs from your position expressed in the May 18, 1998 letter, please contact Thomas Young of my staff at (630) 829-9835 or me at (630) 829-9602.

Sincerely,

Original Signed by

Geoffrey C. Wright, Chief
Materials Inspection Branch 2

Docket No. 030-02271
License No. 24-00167-11

cc: John Eichling, Ph.D., RSO
Carlos A. Perez, M.D., Chairman, RSC
Barry A. Siegel, M.D., Vice Chairman, RSC
Karen Davis, Esq.

bcc: PUBLIC IE07
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