

September 9, 2020

Michelle Hammond U.S. Nuclear Regulatory Commission Region IV Office 1600 E Lamar Boulevard Arlington, TX 76011-4511

RE: Additional commitments for Y-90 amendment request, RAML 50-18244-01.

Dear Ms. Hammond:

In addition to the commitments made in the letters to your office dated August 13, 2020 and September 8, 2020, in regards to Y-90 microspheres we commit to implement "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance", Revision 10.1, dated March 20, 2020.

We acknowledge that by adding this authorization for 35.1000 (Program Code 2240 – Emerging Technology), our NRC inspection frequency will be every 2 years and our fee will not change.

We acknowledge that we have reviewed NRC Information Notice-19-12, published on December 31, 2019, entitled "Recent Reported Medical Events Involving the Administration of Yttrium-90 Microspheres for Therapeutic Medical."

Please contact Kory Kodimer, Ph.D., our consulting Health Physicist, with any questions concerning this additional information. Dr. Kodimer may be contacted at (818) 421-8614 or via email at <u>kory.kodimer@cardinalhealth.com</u>.

Sincerely,

-Atmi

Peter A Stokinger, CNMT Radiation Safety Officer 907-264-1290