



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

June 27, 2022

Mr. Tim Mahilrajan  
Senior Manager – Nuclear Regulatory & EHS  
BWXT Medical, Ltd.  
109 Ramsey Place  
Lynchburg, VA 24501

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION APPROVAL OF BWXT  
MEDICAL, LTD. REQUEST FOR WITHHOLDING INFORMATION FROM  
PUBLIC DISCLOSURE

Dear Mr. Mahilrajan:

BWXT Medical, Ltd. submitted an affidavit dated April 27, 2022, executed by Liza Davis, requesting the information in its response to the U.S. Nuclear Regulatory Commission's (NRC's) request for information dated April 7, 2022, submitted in connection with your amendment request to your sealed safety and device registration certificate be withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 2.390.

The affidavit stated that the submitted information should be considered exempt from mandatory public disclosure because the information is unavailable in other public documents and is of the type that if disclosed publicly, would cause substantial harm to Boston Scientific Corporation, which is the owner of TheraSphere and has a licensing agreement with BWXT Medical, Ltd. to distribute TheraSphere.

We have reviewed your application and the material in accordance with the requirements of 10 CFR 9.17 and 2.390, on the basis of your statements, have determined that the submitted information sought to be withheld contains trade secrets or confidential or privileged commercial or financial information and should be withheld from public disclosure.

Therefore, the information requested to be withheld in the affidavit dated April 27, 2022, will be withheld from public disclosure pursuant to 10 CFR 9.17 and 10 CFR Paragraph 2.390(b)(4) and Section 103(b) of the Atomic Energy Act of 1954, as amended. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the NRC. You also should understand that the NRC may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes your information. In all review situations, if the NRC makes a determination adverse to the above, you will be notified of the date of public disclosure, in advance which will be a reasonable time thereafter.

If you have any questions, please contact me at (301) 415-7138, or by e-mail at [Tomas.Herrera@nrc.gov](mailto:Tomas.Herrera@nrc.gov).

Sincerely,

6/27/2022

X 

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Tomas Herrera

Team Leader

Signed by: Tomas E. Herrera

**Tomas Herrera, Team Leader**  
**Materials Safety Tribal and Liaison Branch**  
**Division of Materials Safety, Security, State,**  
**and Tribal Programs**  
**Office of Nuclear Material Safety**  
**and Safeguards**

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DATE: June 27, 2022

**DISTRIBUTION:**  
SSD Case: 22-07

**ADAMS Accession No. ML22167A206 \*Concurrence via Email**

<b>OFC</b>	NMSS/MSST	NMSS/MSST	NMSS/MSST	NMSS/MSST
<b>NAME</b>	TBrockington	THerrera	LSepulveda*	THerrera
<b>DATE</b>	6/16/22	6/24/22	6/24/22	6/27/22

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