March 13, 2026

Boston Scientific Corporation
Amy Mckinney
Fellow, Regulatory Affairs
300 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K260479
Trade/Device Name: TheraSphere 360™ Y-90 Management Platform
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 12, 2026
Received: February 13, 2026

Dear Amy Mckinney:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260479

Device Name
TheraSphere 360™ Y-90 Management Platform

Indications for Use *(Describe)*
The TheraSphere 360™ Y-90 Management Platform includes Treatment Planning and Activity Calculation functionalities as optional interactive tools intended for calculating the activity of TheraSphere Microspheres required at treatment time based upon the desired dose, lung shunt fraction, anticipated residual waste, and liver mass.

The Treatment Planning and Activity Calculation functionalities include features to aid in TheraSphere Microspheres dose vial selection.

Additionally, the TheraSphere 360 Platform includes optional post-treatment analysis functionalities to be used following treatment with TheraSphere Microspheres. For post-TheraSphere Microspheres treatment, the TheraSphere 360 Platform should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for pre-treatment planning when there is a need for retreatment using TheraSphere Microspheres.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K260479
510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter:	Boston Scientific Corp.
Company Contact Person: Phone: Email:	Ms. Amy E McKinney, MS, RAC Fellow, Regulatory Affairs Boston Scientific Corp 651-287-5096 Amy.mckinney@bsci.com
Alternate Contact Person: Phone: Email:	Ms. Janet Bukovcan Director, Regulatory Affairs Boston Scientific Corp. 613-866-9312 Janet.bukovcan@bsci.com
Device Name:	TheraSphere 360™ Y-90 Management Platform
Device Classification Name:	Medical image management and processing system (LLZ) 21 CFR 892.2050
Review Panel:	Radiology
Predicate Devices / Reference 510(k):	TheraSphere 360™ Y-90 Management Platform (K252547)
Date of Preparation:	February 13, 2026

Device Description:

The TheraSphere 360 Y-90 Management Platform is an end-to-end, browser-based platform that will host a wide range of resources (e.g. radioembolization activity calculations, ordering, tracking, and education) that support Authorized Users of TheraSphere Microspheres.

The TheraSphere 360 Platform includes treatment planning functionality, activity calculation functionality, vial selection and ordering, and post-treatment analysis functionality. The treatment planning functionality and the activity calculation functionality include an interactive tool intended for calculating the activity of TheraSphere Microspheres required at the treatment time based upon the desired dose, lung shunt fraction, anticipated residual waste, and liver mass.

The Vial Selector function allows users to select and order TheraSphere Microspheres dose vials from inventory that match desired results.

The post-treatment analysis functionality is intended as an optional tool for post-treatment evaluation following TheraSphere Microspheres treatment.

Indications For Use:

No changes were made to the Indications for Use.

The TheraSphere 360™ Y-90 Management Platform includes Treatment Planning and Activity Calculation functionalities as optional interactive tools intended for calculating the activity of TheraSphere Microspheres required at treatment time based upon the desired dose, lung shunt fraction, anticipated residual waste, and liver mass.

The Treatment Planning and Activity Calculation functionalities include features to aid in TheraSphere Microspheres dose vial selection.

Additionally, the TheraSphere 360 Platform includes optional post-treatment analysis functionalities to be used following treatment with TheraSphere Microspheres. For post-TheraSphere Microspheres treatment, the TheraSphere 360 Platform should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for pre-treatment planning when there is a need for retreatment using TheraSphere Microspheres.

Technological Comparison:

This Special 510(k) was submitted for TheraSphere 360 V2.0 software. Changes in this 510(k) included modifications to allow for Any Day Dosing, which imports the actual vial calibration date instead of using a preset calibration date of Sunday, noon. This change allows users to select vials based on Days Post Calibration instead of Week 1 / Week 2. Additionally, user interface changes were made to provide more information to the user during vial selection, provide enhanced filtering and sorting capabilities, and make visualizations more user friendly.

Any Day Dosing and the associated user interface changes did not change the technological principles or principles of operation of TheraSphere 360 V2.0 from the previously cleared TheraSphere 360 software version.

The table below provides a summary comparison of the submitted device compared to the predicate device:

Characteristic	TheraSphere™ 360 Y-90 Management Platform V2.0	TheraSphere™ 360 Y-90 Management Platform V1.1.2	Comment
Indications for Use	The TheraSphere 360 Y-90 Management Platform includes Treatment Planning and Activity Calculation functionalities as optional interactive tools intended for calculating the activity of TheraSphere Microspheres required at treatment time based upon the desired dose, lung shunt fraction, anticipated residual waste, and liver mass. The Treatment Planning and Activity Calculation	The TheraSphere 360 Y-90 Management Platform includes Treatment Planning and Activity Calculation functionalities as optional interactive tools intended for calculating the activity of TheraSphere Microspheres required at treatment time based upon the desired dose, lung shunt fraction, anticipated residual waste, and liver mass. The Treatment Planning and Activity Calculation functionalities include features to aid in TheraSphere Microspheres dose	**Identical**

Characteristic	TheraSphere™ 360 Y-90 Management Platform V2.0	TheraSphere™ 360 Y-90 Management Platform V1.1.2	Comment
	functionalities include features to aid in TheraSphere Microspheres dose vial selection. Additionally, the TheraSphere 360 Platform includes optional post-treatment analysis functionalities to be used following treatment with TheraSphere Microspheres. For post-TheraSphere Microspheres treatment, the TheraSphere 360 Platform should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for pre-treatment planning when there is a need for retreatment using TheraSphere Microspheres.	vial selection. Additionally, the TheraSphere 360 Platform includes optional post-treatment analysis functionalities to be used following treatment with TheraSphere Microspheres. For post-TheraSphere Microspheres treatment, the TheraSphere 360 Platform should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for pre-treatment planning when there is a need for retreatment using TheraSphere Microspheres.	
Principles of Operation	Medical Internal Radiation Dose (MIRD) schema for dosimetry calculations	Medical Internal Radiation Dose (MIRD) schema for dosimetry calculations	**Identical**
Device Functionalities	Contains medical device functionalities which utilize radioembolization activity calculations to determine the dose of TheraSphere Microspheres required at treatment time.	Contains medical device functionalities which utilize radioembolization activity calculations to determine the dose of TheraSphere Microspheres required at treatment time.	**Identical**

Summary of Performance Data

Performance testing confirmed that the TheraSphere 360 V2.0 software performs safely and effectively and does not introduce any new or different safety risks. The TheraSphere 360 V2.0 medical device functions underwent full system and software verification testing, including unit and integration testing and cybersecurity evaluation, to ensure that the product meets the defined system and software requirements. A design validation evaluation was conducted to ensure that the platform meets defined user needs. Verification and validation testing, including a usability evaluation, successfully demonstrated that the medical device functions and algorithms meet requirements and user needs, confirming safety and effectiveness of TheraSphere 360 V2.0 software and substantial equivalence to the predicate device.

Clinical testing was not required to validate TheraSphere 360 V2.0 software.

Conclusion:

In conclusion, the TheraSphere 360 Y-90 Management Platform V2.0 medical device functions were

evaluated against the predicate device and found to be substantially equivalent on the basis that 1) the indications for use are unchanged, and 2) the technology of the TheraSphere 360 Platform medical device functions is the same as the predicate device and no new or different issues of safety and effectiveness were raised.