



October 28, 2025

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

Re: K252547

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: August 12, 2025  
Received: August 12, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Lora D. Weidner". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

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

## Indications for Use

510(k) Number (if known)  
K252547

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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**K252547**  
**510(k) SUMMARY**

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

<b>Submitter:</b>	Boston Scientific Corp.
<b>Company Contact Person:</b>  Phone: Email:	Ms. Amy E McKinney, MS, RAC Fellow, Regulatory Affairs Boston Scientific Corp 651-287-5096 Amy.mckinney@bsci.com
<b>Alternate Contact Person:</b>  Phone: Email:	Ms. Janet Bukovcan Director, Regulatory Affairs Boston Scientific Corp. 613-801-1848 Janet.bukovcan@bsci.com
<b>Device Name:</b>	TheraSphere 360™ Y-90 Management Platform
<b>Device Classification Name:</b>	Medical image management and processing system (LLZ) 21 CFR 892.2050
<b>Review Panel:</b>	Radiology
<b>Predicate Devices / Reference 510(k):</b>	Simplicit <sup>90</sup> Y (K182016)
<b>Date of Preparation:</b>	October 16, 2025

**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:

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:

The technological characteristics of the TheraSphere 360 Platform medical device functions are similar to those of the predicate device and do not raise issues of safety or effectiveness. The key differences are related to how the software is accessed and how data is input into the device. TheraSphere 360 is accessed online via a web-based portal and uses manual physician data input, whereas the predicate device is installed on a user's computing platform and incorporates the use of digital medical images and tools to register and segment the images. TheraSphere 360 and the predicate have the same principles of operation, and both utilize single-compartment MIRD schema for the dosimetry calculations, in accordance with the TheraSphere Microspheres System labeling.

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

Characteristic	TheraSphere™ 360 Y-90 Management Platform Indications for Use	Predicate Device: Simplicity <sup>90</sup> Y (K182016) Indications for Use	Comment
Indications for Use	<p>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.</p> <p>The Treatment Planning and Activity Calculation functionalities include features to aid in TheraSphere Microspheres dose vial selection.</p>	<p>Simplicity<sup>90</sup>Y is a standalone software device that is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images.</p> <p>Simplicity<sup>90</sup>Y supports the reading, rendering and display of a range of DICOM compliant imaging and related formats including but not limited to CT, PT, NM, SPECT, MR, SC, RTSS. Simplicity<sup>90</sup>Y enables the saving of sessions in a proprietary format as well as the export of formats including CSV and PDF files.</p> <p>Simplicity<sup>90</sup>Y is indicated, as an accessory to TheraSphere, to</p>	<p><b>Similar.</b></p> <p>The indications of the TheraSphere 360 Y-90 Management Platform are encompassed within the indications of Simplicity<sup>90</sup>Y and represent a narrower scope.</p>

Characteristic	TheraSphere™ 360 Y-90 Management Platform Indications for Use	Predicate Device: Simplicit <sup>90</sup> Y (K182016) Indications for Use	Comment
	<p>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.</p>	<p>provide pre-treatment dosimetry planning support including Lung Shunt Fraction estimation (based on planar scintigraphy) and liver single-compartment MIRDO schema dosimetry, in accordance with TheraSphere labelling.</p> <p>Simplicit<sup>90</sup>Y provides tools to create, transform, and modify contours/Regions of Interest for calculation of Lung Shunt Fraction and Perfused Volume. Simplicit<sup>90</sup>Y includes features to aid in TheraSphere dose vial selection, dose vial ordering and creation of customizable reports.</p> <p>Simplicit<sup>90</sup>Y is indicated for post-treatment dosimetry and evaluation following Yttrium-90 (Y-90) microsphere treatment. Simplicit<sup>90</sup>Y provides tools to create, transform, and modify contours/Regions of Interest for the user to define objects in medical image volumes to support TheraSphere post-Y-90 treatment calculation and evaluation. The objects include, but are not limited to, tumors and normal tissues, and liver volumes. Simplicit<sup>90</sup>Y is indicated for registration, fusion display and review of medical images allowing medical professionals to incorporate images, such as CT, MRI, PET, CBCT and SPECT in TheraSphere Yttrium-90 (Y-90) microspheres pre-treatment planning and post-Y-90 treatment evaluation.</p> <p>For post-Yttrium-90 (Y-90) treatment, Simplicit<sup>90</sup>Y should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for the case where there is a need for retreatment using Y-90 microspheres.</p>	
<b>Software Access Method</b>	Multi-function standalone software that is accessed online.	Standalone software that is installed on the user's computing platform.	<b>Different.</b>  Both the predicate and

Characteristic	TheraSphere™ 360 Y-90 Management Platform Indications for Use	Predicate Device: Simplicit <sup>90</sup> Y (K182016) Indications for Use	Comment
			the proposed device are standalone software; however, the proposed device is available online and does not require installation. The access method of the device does not impact the substantial equivalence of the medical device functions of TheraSphere 360 to Simplicit <sup>90</sup> Y.
<b>Principles of Operation</b>	Medical Internal Radiation Dose (MIRD) schema for dosimetry calculations	Medical Internal Radiation Dose (MIRD) schema for dosimetry calculations	<b>Identical.</b>
<b>Device Functionalities</b>	Contains medical device functionalities which utilize radioembolization activity calculations to determine the dose of TheraSphere Microspheres required at treatment time.	<p>Contains medical device functionalities which utilize radioembolization activity calculations to determine the dose of TheraSphere Microspheres required at treatment time.</p> <p>Additionally,</p> <p>Simplicit<sup>90</sup>Y is a medical image and information management system that is intended to receive, transmit, store, retrieve, display and process digital medical images, as well as create, display and print reports from those images.</p> <p>Simplicit<sup>90</sup>Y provides the user with the means to display, register and fuse medical images from multiple modalities.</p> <p>Simplicit<sup>90</sup>Y provides tools to create, transform, and modify contours for the user to define objects in medical image volumes for use in TheraSphere® pre-treatment dosimetry planning and for post-treatment dosimetry. The objects include, but are not limited to, tumors and normal tissues.</p>	<b>Similar.</b> TheraSphere 360 and Simplicit <sup>90</sup> Y differ in that TheraSphere 360 contains a subset of the device functionality of Simplicit <sup>90</sup> Y.

## **Summary of Performance Data**

Performance testing confirmed that the TheraSphere 360 Platform performs safely and effectively and does not introduce any new or different safety risks. The TheraSphere 360 Platform 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 and substantial equivalence to the predicate device.

Clinical testing was not required to validate the TheraSphere 360 Y-90 Management Platform medical device functions.

## **Conclusion:**

In conclusion, the TheraSphere 360 Y-90 Management Platform medical device functions were evaluated against the predicate device and found to be substantially equivalent on the basis that 1) the indications for use of the TheraSphere 360 Platform consist of a narrower scope than those of the predicate device, and 2) the technology of the TheraSphere 360 Platform medical device functions is similar to the predicate device and the differences do not raise any new or different issues of safety and effectiveness.