October 18, 2024

Boston Scientific Corp.
Dana Borris
Regulatory Affairs Specialist II
1 Scimed Place
Maple Grove, Minnesota 55311

Re: K243245
Trade/Device Name: IceSeed 1.5 CX Straight Needle (H7493968333170); IceSphere1.5 CX Straight Needle (H7493968435730); IceRod 1.5 CX Straight Needle (H7493968535330)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: October 11, 2024
Received: October 11, 2024

Dear Dana Borris:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2024.10.18 14:35:27 -04'00'

For
Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243245

Device Name
IceSeed 1.5 CX Straight Needle (H7493968333170);
IceSphere1.5 CX Straight Needle (H7493968435730);
IceRod 1.5 CX Straight Needle (H7493968535330)

Indications for Use *(Describe)*
The Boston Scientific disposable IceRod Cryoablation Needle, IceSphere Cryoablation Needle, IceSeed Cryoablation Needle, IcePearl Cryoablation Needle, and IceForce Cryoablation Needle (CX Needles) are meant to be connected to a Boston Scientific ICEfx Cryoablation System or Visual-ICE Cryoablation System when performing cryoablative tissue destruction through application of extremely cold temperatures. The needles are intended to convert high-pressure gas to either a very cold Freezing application or to a warm Thawing application.

The Boston Scientific CX Needles, when used with ICEfx Cryoablation System or Visual-ICE Cryoablation System, are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. The CX Needles are designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, and skin lesions) by the application of extremely cold temperatures.

The CX Needles have the following specific indications:
• Urology - Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH)
• Oncology - Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention. Palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard radiation therapy.
• Dermatology – Ablation or freezing of skin cancers and other cutaneous disorders. Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin
• Gynecology – Ablation of malignant neoplasia or benign dysplasia of the female genitalia
• General surgery – Palliation of tumors of the rectum, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas
• ENT – Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth
• Thoracic surgery – (with the exception of cardiac tissue)
• Proctology – Ablation of benign or malignant growths of the anus or rectum

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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K243245
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 1 Scimed Pl Maple Grove MN 55311 United States
Company Contact Person:	Dana Borris Regulatory Affairs Specialist Boston Scientific Phone: 763-494-1850 Email: Dana.Borris@bsci.com
Alternate Contact Person:	Rachel Owens Sr. Manager, Regulatory Affairs Boston Scientific Phone: 763-273-6865 Email: rachel.owens@bsci.com
Device Name:	IceSeed 1.5 CX Straight Needle (H7493968333170) IceSphere 1.5 CX Straight Needle (H7493968435730) IceRod 1.5 CX Straight Needle (H7493968535330)
Device Classification Name:	Cryosurgical unit and accessories Regulation Number: 21 CFR 878.4350 Product Code: GEH
Predicate Device 510(k):	IceSeed 1.5 CX 90º Cryoablation Needle (K232635) IceSphere 1.5 CX 90º Cryoablation Needle (K181741) IceRod 1.5 CX 90º Cryoablation Needle (K140584)
Date of Preparation:	October 15, 2024

Device Description:

Boston Scientific Corporation's (BSC) IceSeed 1.5 CX Straight Cryoablation Needle, IceSphere 1.5 CX Straight Cryoablation Needle, and IceRod 1.5 CX Straight Cryoablation Needle (hereafter referred collectively as the Straight Needles) are sterile, single use, disposable devices used in conjunction with a Boston Scientific cryoablation system for cryoablative destruction of tissue during surgical procedures under CT guidance. The Straight CX Needles are disposable 1.5 mm needles that have a sharp cutting tip, a color-coded handle, a gas tube, and a connector. The needles convert high-pressure gas to either a very cold freezing application or to a warm thawing application. Active tissue thawing may also be achieved by activating the heating element inside the Straight CX Needles.

The table below provides a summary comparison of the submitted devices compared to the predicate devices.

Description	Submitted Devices: IceSeed 1.5 CX Straight Cryoablation Needle, IceSphere 1.5 CX Straight Cryoablation Needle, and IceRod 1.5 CX Straight Cryoablation Needle	Predicate Devices: IceSeed 1.5 CX 90º Cryoablation Needle (K232635), IceSphere 1.5 CX 90º Cryoablation Needle (K181741), and IceRod 1.5 CX 90º Cryoablation Needle (K140584)
Intended Use / Indications for Use	The Boston Scientific disposable IceRod Cryoablation Needle, IceSphere Cryoablation Needle, IceSeed Cryoablation Needle, IcePearl Cryoablation Needle, and IceForce Cryoablation Needle (CX Needles) are meant to be connected to a Boston Scientific ICEfx Cryoablation System or Visual-ICE Cryoablation System when performing cryoablative tissue destruction through application of extremely cold temperatures. The needles are intended to convert high-pressure gas to either a very cold Freezing application or to a warm Thawing application. The Boston Scientific CX Needles, when used with ICEfx Cryoablation System or Visual-ICE Cryoablation System, are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. The CX Needles are designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, and skin lesions) by the application of extremely cold temperatures. The CX Needles have the following specific indications: • Urology - Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH) • Oncology - Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention. Palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard radiation therapy. • Dermatology – Ablation or freezing of skin cancers and other cutaneous disorders. Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin • Gynecology – Ablation of malignant neoplasia or benign dysplasia of the female genitalia • General surgery – Palliation of tumors of the rectum, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas • ENT – Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth • Thoracic surgery – (with the exception of cardiac tissue) • Proctology – Ablation of benign or malignant growths of the anus or rectum	
Tip technology	Closed trocar tip	Closed trocar tip
Shaft working length	175mm	175 mm
Shaft Diameter	1.5 mm	1.5 mm
Markings: Thin Marks	**IceSeed** and **IceSphere:** 45 mm from tip in 5 mm intervals **IceRod:** Starts 55 mm from tip in 5 mm intervals	**IceSeed** and **IceSphere:** 45 mm from tip in 5 mm intervals **IceRod:** Starts 55 mm from tip in 5 mm intervals
Markings: Thick Marks	**IceSeed** and **IceSphere:** 40 mm from tip in 10 mm intervals **IceRod:** Starts 60 mm from tip in 10 mm intervals	**IceSeed** and **IceSphere:** 40 mm from tip in 10 mm intervals **IceRod:** Starts 60 mm from tip in 10 mm intervals

Description	Submitted Devices: IceSeed 1.5 CX Straight Cryoablation Needle, IceSphere 1.5 CX Straight Cryoablation Needle, and IceRod 1.5 CX Straight Cryoablation Needle	Predicate Devices: IceSeed 1.5 CX 90º Cryoablation Needle (K232635), IceSphere 1.5 CX 90º Cryoablation Needle (K181741), and IceRod 1.5 CX 90º Cryoablation Needle (K140584)
Length of low friction coating on shaft	**IceSeed** and **IceSphere:** Begins 4.5mm from tip; ends 35mm from tip **IceRod:** Begins 4.5mm from tip; ends 50mm from tip	**IceSeed** and **IceSphere:** Begins 4.5mm from tip; ends 35mm from tip **IceRod:** Begins 4.5mm from tip; ends 50mm from tip
Active zone Indicator	**IceSeed** and **IceSphere:** Starts 55 mm from tip; 10mm band **IceRod:** Starts 70 mm from tip; 10mm band	**IceSeed** and **IceSphere:** Starts 55 mm from tip; 10mm band **IceRod:** Starts 70 mm from tip; 10mm band
Freezing cryogen	Argon 99.995%	Argon 99.995%
Thawing gas	Helium 99.998%	Helium 99.998%
Isotherm diameter	**IceSeed:** -40°C: 15 ± 3 mm -20°C: 24 ± 3 mm 0°C: 37.5 ± 3 mm **IceSphere:** -40°C: 16 ± 3 mm -20°C: 26 ± 3 mm 0°C: 39 ± 3 mm **IceRod:** -40°C: 17 ± 3 mm -20°C: 28 ± 3 mm 0°C: 43 ± 3 mm	**IceSeed:** -40°C: 15 ± 3 mm -20°C: 24 ± 3 mm 0°C: 37.5 ± 3 mm **IceSphere:** -40°C: 16 ± 3 mm -20°C: 26 ± 3 mm 0°C: 39 ± 3 mm **IceRod:** -40°C: 17 ± 3 mm -20°C: 28 ± 3 mm 0°C: 43 ± 3 mm
Isotherm height	**IceSeed:** -40°C: 21 ± 4 mm -20°C: 28 ± 4 mm 0°C: 41 ± 4 mm **IceSphere:** -40°C: 24 ± 4 mm -20°C: 32 ± 4 mm 0°C: 45 ± 4 mm **IceRod:** -40°C: 41 ± 4 mm -20°C: 47 ± 4 mm 0°C: 60 ± 4 mm	**IceSeed:** -40°C: 21 ± 4 mm -20°C: 28 ± 4 mm 0°C: 41 ± 4 mm **IceSphere:** -40°C: 24 ± 4 mm -20°C: 32 ± 4 mm 0°C: 45 ± 4 mm **IceRod:** -40°C: 41 ± 4 mm -20°C: 47 ± 4 mm 0°C: 60 ± 4 mm

In summary, the submitted Straight CX Cryoablation Needles have the same technology and principle of operation as the predicate devices.

Indications for Use / Intended Use:
The Boston Scientific disposable IceRod Cryoablation Needle, IceSphere Cryoablation Needle, IceSeed Cryoablation Needle, IcePearl Cryoablation Needle, and IceForce Cryoablation Needle (CX Needles) are meant to be connected to a Boston Scientific ICEfx Cryoablation System or Visual-ICE Cryoablation System when performing cryoablative tissue destruction through application of extremely cold temperatures. The needles are intended to convert high-pressure gas to either a very cold Freezing application or to a warm Thawing application.

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• ENT – Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth
• Thoracic surgery – (with the exception of cardiac tissue)
• Proctology – Ablation of benign or malignant growths of the anus or rectum

Summary of Performance Data and Substantial Equivalence:
Verification testing was conducted on the Straight CX Cryoablation Needles to ensure that the design, functionality, and performance met all the specified requirements and that the features of the needle satisfy its intended use. Testing was conducted according to protocols based on international standards and in-house requirements. Verification testing included functional testing, system compatibility testing, and labeling review. Functional testing assessed whether the electrical heater requirements and functional requirements were met. System compatibility testing ensured the needle would operate with a Boston Scientific Cryoablation System. Labeling verification evaluated instructions for use and labeling accuracy with respect to design requirements and risk mitigations. Test results demonstrated that the Straight CX Cryoablation Needles meets defined specifications, is substantially equivalent to the predicate devices, and does not raise any new issues of safety and effectiveness for its intended use.

Conclusion (Statement of Equivalence):
As the indications for use and fundamental scientific technology have not changed, verification testing provided in this Special 510(k) Premarket Notification supports a determination that the Straight CX Cryoablation Needles are substantially equivalent to the legally marketed predicate devices, with regard to performance, safety, and effectiveness for its intended use.