March 13, 2024

Boston Scientific
Benjamin Van Santen
Regulatory Affairs Specialist
1 SciMed Place
Maple Grove, Minnesota 55311

Re: K234002
Trade/Device Name: ICEfx™ Cryoablation System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: December 18, 2023
Received: December 19, 2023

Dear Benjamin Van Santen:

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.

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,

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234002

Device Name
ICEfx™ Cryoablation System

Indications for Use *(Describe)*
The ICEfx™ Cryoablation System is 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. This system is designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, and skin lesions) by the application of extremely cold temperatures.

The ICEfx Cryoablation System has 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.

510(k) Summary

Device Trade Name: ICEfx™ Cryoablation System

Manufacturer:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752

Manufacturing Site:
Boston Scientific Corporation
4100 Hamline Ave North
St. Paul, MN 55112

Primary Contact:
Ben Van Santen
Regulatory Affairs Specialist
Boston Scientific Corporation
Cell: 763-923-5435
Email: benjamin.vansanten@bsci.com

Alternate Contact:
Rachel Owens
Senior Regulatory Affairs Manager
Boston Scientific Corporation
Cell: 763-273-6865
Email: Rachel.Owens@bsci.com

Date Prepared: December 18, 2023

Classifications: 21 CFR 878.4350 Cryosurgical unit and accessories

Class: II

Product Codes: GEH

Primary Predicate: Visual-ICE™ Cryoablation System (K230551)

Additional Predicate: N/A

Device Description:

The ICEfx Cryoablation System is a mobile system intended for cryoablative tissue destruction using a minimally invasive procedure. The system is computer-controlled with a touch screen user interface that allows the user to control and monitor the procedure. The therapy delivered by the system is based on the Joule-Thomson effect displayed by compressed gases. The ICEfx System uses high-pressure argon gas that circulates through closed-tip cryoablation needles to induce tissue freezing. Active tissue thawing is achieved by the use of CX technology in which a heating element inside the cryoablation needle can be energized to cause thawing.

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

Description of Submitted Device: ICEfx Cryoablation System	**Comments related to Predicate:** Visual-ICE Cryoablation System (K230551)
Design and Construction	
Console	Similar to predicate; ICEfx is smaller and lighter weight
Needle ports	ICEfx contains fewer needle ports
Channel Lock	Same as predicate
User interface	Similar to predicate; touchscreen with equivalent function and features
Needle Interface	Same as predicate
Performance and Function	
Principles of Operation: Freezing / Thawing	Same as predicate; ICEfx does not support the option for helium thaw
CX Technology for Electrical Thawing	Same as predicate
Needle Compatibility	Same as predicate; ICEfx supports fewer needles

In summary, the submitted ICEfx Cryoablation System has the same technology and principle of operation as the predicate device.

Performance Testing Summary:

A full battery of verification and validation testing was conducted on the ICEfx Cryoablation System to ensure that the design, functionality, and performance met the specified requirements. Testing was conducted according to protocols based on international standards and in-house requirements. Testing included system testing, electrical testing, mechanical testing, packaging and labeling testing, software testing, design and usability testing.

System testing assessed whether the functional requirements of the system as a whole were satisfied by the design. Mechanical testing evaluated the mechanical robustness of the system and sub-systems, functional testing of the gas system, and tests of mechanical safety requirements. Electrical testing assessed the functional aspects of the circuit assemblies, tests of electromagnetic compatibility and immunity (EMC/EMI), and tests of electrical safety requirements. Labeling verification evaluated user manual and labeling accuracy with respect to design requirements and risk mitigations. Software testing exercised individual units of software as well as tests of the functionality of the entire software package. Validation testing included design and usability testing. Test results demonstrated that the ICEfx Cryoablation System meets defined specifications, is substantially equivalent to the predicate device, and does not raise any new issues of safety and effectiveness for its intended use.

Additionally, the safety and effectiveness of use of the predicate Visual-ICE Cryoablation System for pain palliation of metastatic lesions in bone has been evaluated in a clinical study. Results of the clinical study demonstrated that the specific use did not introduce new risks not normally associated with the general use of the device and demonstrated the safety and effectiveness of the system when used for the specific indication of pain palliation of metastatic lesions in bone.

Conclusion (Substantial Equivalence):

The subject device is identical in technology and functionality to the primary predicate Visual-ICE Cryoablation System. The subject Traditional 510(k) proposes a specific indication which represents a subset of the general indications cleared for the Visual-ICE Cryoablation System. The data provided in this Traditional 510(k) Premarket Notification supports a determination that the ICEfx Cryoablation System is substantially equivalent to the legally marketed predicate device, with regard to performance, safety, and effectiveness for its intended use.