August 8, 2023

Boston Scientific Corporation
Amy Mckinney
Regulatory Affairs Fellow
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K230551
Trade/Device Name: Visual-ICE Cryoablation System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: February 28, 2023
Received: February 28, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230551

Device Name
Visual-ICE Cryoablation System

Indications for Use *(Describe)*
The Visual-ICE™ Cryoablation System is intended for cryoablative destruction of tissue during surgical procedures. The Visual-ICE™ 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. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, and skin lesions.

The Visual-ICE 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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K230551

Device Trade Name:	Visual-ICE 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:	Amy McKinney, MS, RAC Fellow, Regulatory Affairs Boston Scientific Corporation Office: 651-287-5096 Cell: 979-236-1622 Email: amy.mckinney@bsci.com
Alternate Contact:	Rebeka Stoltman, MBA, RAC Director, Regulatory Affairs Boston Scientific Corporation Cell: 952-457-9228 Email: Rebeka.stoltman@bsci.com
Date Prepared:	July 7, 2023
Classifications:	21 CFR 878.4350 Cryosurgical unit and accessories
Class:	II
Product Codes:	GEH
Primary Predicate:	Visual-ICE™ Cryoablation System (K113860, K143564, K152133)
Additional Predicate:	N/A

Indications For Use:
The Visual-ICE™ Cryoablation System is intended for cryoablative destruction of tissue during surgical procedures. The Visual-ICE™ 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. The system is designed to destroy tissue by the application of extreme cold temperatures

including prostate and kidney tissue, liver metastases, tumors, and skin lesions.

The Visual-ICE 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

Device Description:
The Visual-ICE Cryoablation System is a mobile console system intended for cryoablative tissue destruction using a minimally invasive procedure. The Visual-ICE™ System uses high-pressure argon gas that circulates through closed-tip cryoablation needles to induce tissue freezing. Active tissue thawing is achieved by circulating helium gas through the needles or, alternatively, using Boston Scientific's i-Thaw® technology in which a heating element inside the cryoablation needle can be energized to cause thawing.

Predicate Device:
Boston Scientific Corporation submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Visual-ICE

Cryoablation System is substantially equivalent in indications, design principles, and performance to the predicate Visual-ICE Cryoablation System.

Non-Clinical Performance Testing Summary:
A full battery of verification and validation testing was conducted on the Visual-ICE 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.

Verification testing included the following:

- System Verification Testing – verified functional requirements associated with the complete system
- Mechanical Verification Testing – verified mechanical requirements associated with the gas components, chassis, and shipping of the packaged system
- Electrical Verification Testing – verified electrical performance requirements, including IEC 60601-1 and IEC 60601-1-2 requirements for safety and emissions
- Software Verification Testing – verified all software requirements
- Labeling and Packaging Testing – verified requirements associated with labels, the user manual, and shipping carton.

Validation testing included the following:

- Design and Usability Testing – validated the Visual-ICE™ Cryoablation System in a simulated use environment to assess usability of the system, as well as to demonstrate that the system offered the required functionality for a cryoablation procedure
- Animal Cadaver Study – validated the system in a representative operating room to assess usability of the system, the ability to complete a cryoablation procedure in a realistic setting with an animal cadaver, and to assess interference between the cryoablation system and operating room monitoring equipment.

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. 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 and animal testing. Test results demonstrated that the Visual-ICE 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.

Acceptance criteria for all verification and validation testing were based on the pre-defined system and software requirements. The Visual-ICE Cryoablation System passed all verification and validation testing determining that the design outputs met the design inputs, and the Visual-ICE Cryoablation System is validated for use.

Clinical Testing Summary:
The safety and effectiveness of use of the Visual-ICE™ Cryoablation System for pain palliation of metastatic lesions in bone was evaluated in ‘Multicenter Study of Cryoablation for Palliation of

Painful Bone Metastases (MOTION)' to assess the efficacy of cryoablation for palliation of painful metastases in patients with metastatic lesions involving bone who had failed, were not candidates for, or were not experiencing adequate pain relief from current pain therapies (e.g., radiation, analgesics). The MOTION clinical trial was a multi-center (11 sites: 7 in US and 4 in Europe), single-arm, prospective, nonrandomized clinical trial assessing the efficacy of cryoablation for palliation of painful metastases in patients (n=66).

The median age of study subjects was 60.5 years (interquartile range: 51 to 70 years), 53% of subjects were male, and the median body mass index (BMI) was 23.6 kg/m^2. Information on race and ethnicity is not available for approximately half of the study subjects; these subjects were enrolled at sites in France where collection of information on the race and ethnicity of clinical trial subjects is not permitted. Of the 53% of subjects with data on race and ethnicity, most were Caucasian (77.2%) and non-Hispanic (97.1%). Eight (8) patients were African American (22.8%).

The Visual-ICE™ Cryoablation System, when used in accordance with cleared indications, has been demonstrated to have an acceptable risk profile that is equivalent to predicate devices. A 2-point reduction from baseline in BPI score for worst pain in the last 24 hours was achieved with respect to mean change and median change at week 1 and every subsequent timepoint through week 24. When evaluated using measures of worst pain reduction and decrease in analgesic usage as outlined by the International Bone Metastases Consensus Working Party, 57.8% of patients achieved complete or partial response by week 1, with scores improving until the maximum percentage of patients (70%) achieved complete or partial response at week 12. Furthermore, treatment with the Visual-ICE Cryoablation System led to consistent improvements from baseline in subjects' quality of life, as assessed using the BPI-SF Pain Interference tool.

The results of the MOTION Study demonstrate an equivalent risk profile to the predicate device, with no new or increased risks. Three (3) subjects experienced a total of 3 SAEs (abdominal pain, hematoma, and skin burn/frostbite). All event types are anticipated and captured in the cleared system labelling.

Results of this 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.

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 proposed specific indication is supported by clinical data demonstrating safety and effectiveness when used for the specific indication. Results of clinical testing demonstrated no new risks associated with the specific indication when used as indicated.

Conclusion:
The subject device and the predicate device are identical in intended use, technological characteristics, materials of manufacture, packaging, and sterilization. The clinical data provided in this submission support expansion of the general system indications to include specific indications for pain palliation of metastatic lesions in bone. The data included in this submission demonstrate substantial equivalence to the predicate device listed above.