October 29, 2024

AtriCure, Inc.
Ronit Shah
Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K243157
Trade/Device Name: AtriCure cryoICE BOX (ACM)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 30, 2024
Received: September 30, 2024

Dear Ronit Shah:

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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2024.10.29 11:06:03 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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.*

Submission Number *(if known)*

K243157

Device Name

AtriCure cryoICE BOX (ACM)

Indications for Use *(Describe)*

The AtriCure cryoICE BOX is a non-sterile, reusable medical device which delivers cryogenic energy, namely nitrous oxide, to AtriCure's cryo-ablation PROBES.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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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**

## I. Applicant Information

**Manufacturer:** AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040
P: 513-755-4100

**Contact Person:** Ronit Shah
Regulatory Affairs Specialist

**Date Prepared:** September 30, 2024

## II. Device Information

**Proprietary Name:** AtriCure® cryoICE® BOX

**Common Name:** Cryo Surgical Unit and Accessories

**Classification:** Unit, Cryosurgical, Accessories
Surgical, General and Plastic Surgery, CFR 878.4350
Class II, Product Code: GEH
Classification Panel: General and Plastic Surgery

**Predicate Device:** AtriCure Cryo Module (K142203, November 25, 2014)

## III. Device Description

The AtriCure cryoICE BOX (ACM) is an electro-mechanical cryogenic surgical system that delivers a Nitrous Oxide ($N_2O$) cryo-genic energy source to a PROBE to create lines of ablation through tissue. The ACM includes single use PROBES (not part of this submission), Component and Accessories. The ACM provides controlled lesion forming temperature that is below -40°C (-40°F).

In addition to the Activation Button on the front panel of the ACM, an accessory Footswitch can also be used to activate and terminate the cryo ablation cycle.

The ACM is designed to operate only with AtriCure's PROBES. Refer to the AtriCure's PROBE Instruction for Use for detailed use and description.

### Intended Use / Indications for Use

The AtriCure cryoICE BOX is a non-sterile, reusable medical device which delivers cryogenic energy, namely nitrous oxide, to AtriCure's cryo-ablation PROBES.

## IV. Comparison of Technological Characteristics with the Predicate Device (AtriCure Cryo Module – K142203)

| # | Feature | Previously cleared AtriCure Cryo Module (K142203) | Modified AtriCure cryoICE BOX (Subject) |
|---|---|---|---|
| 1 | Proprietary Name | AtriCure Cryo Module | AtriCure cryoICE Box |
| 2 | Device Classification | Device, Surgical Cryogenic Cryogenic Surgical Device, 21 CFR 882.4250<br><br>Product Codes: GEH, GXH | Unit, Cryosurgical, Accessories Surgical, General and Plastic Surgery, CFR 878.4350<br><br>Product Code: GEH |
| 3 | Regulatory Class | Class II | Class II |
| 4 | FDA Division | Neurology | General and Plastic Surgery |
| 5 | Performance Standards | No performance standards applicable to this product have been promulgated by FDA | No performance standards applicable to this product have been promulgated by FDA |
| 6 | Indications for Use | The AtriCure Cryo Module is a nonsterile, reusable device which delivers cryogenic energy, namely nitrous oxide, to AtriCure's cryo-ablation probes. | The AtriCure cryoICE BOX is a non-sterile, reusable medical device which delivers cryogenic energy, namely nitrous oxide, to AtriCure's cryo-ablation PROBES. |
| 7 | Operating Principle | Joule-Thompson Effect | Joule-Thompson Effect |
| 8 | Energy Used | Nitrous Oxide | Nitrous Oxide |
| 9 | Power Source | Mains Powered | Mains Powered |
| 10 | Power Specification | 115 VAC, 50/60 Hz (nominal) | 115 VAC, 50/60 Hz (nominal) |
| 11 | Typical Minimum Operating Steady State Probe Temperature | Less than -55°C | Less than -55°C |
| 12 | Software version | V6.02 | V6.10 |
| 13 | Gas Purge System | Automatic | Automatic |
| 14 | Freeze Timer | Manual or Automatic | Manual or Automatic |

- The devices have the same intended use.
- No changes were made to the operating principle.
- No changes to the overall design or function of the devices.

## V. Performance Data

The bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the previously cleared AtriCure Cryo Module. The AtriCure cryoICE BOX device met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared AtriCure Cryo Module. No new safety or performance issues were raised during testing.

## VI. Conclusions

AtriCure has demonstrated that the modifications made to the AtriCure cryoICE BOX are substantially equivalent in fundamental design, technology, function, device materials, packaging, operating principle, and intended use / indication for use as the previously cleared AtriCure Cryo Module per K142203.