November 7, 2022

Medtronic
Sarah Meyer
Senior Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K222873
Trade/Device Name: Attain Command + SureValve and Attain Select II + SureValve Delivery Systems
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 21, 2022
Received: September 22, 2022

Dear Sarah Meyer:

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,

Hetal B. Patel -S

Hetal Odobasic
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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)*
K222873

Device Name
Attain Command + SureValve Delivery System

Indications for Use *(Describe)*
The delivery system is intended for introducing transvenous devices and leads into vessels of the left heart via the coronary sinus and into the right ventricle.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

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)*

K222873

Device Name

Attain Select II +SureValve Delivery System

Indications for Use *(Describe)*

The Attain Select II + SureValve delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus, left-heart venous anatomy, and the right ventricle. For left heart use, the delivery catheter system is indicated for use with outer guide catheters. For right ventricle use, the delivery catheter system is indicated for use without an outer guide catheter.

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.**

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# 510(k) Summary

**Date Prepared:** September 21, 2022

**Submitter:** Medtronic, Inc.
Medtronic Cardiac Rhythm Management
8200 Coral Sea Street N.E.
Mounds View, MN 55112
Establishment Registration Number: 2182208

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## General Information

**Trade Name:** Attain Command™ + SureValve™ Delivery System
Attain Select™ II + SureValve™ Delivery System

**Common Name:** Catheter delivery system

**Regulation Number:** 21 CFR 870.1250

**Product Code:** DQY

**Classification:** Class II

**Classification Panel:** Cardiovascular

**Predicate Device:** *(Attain Command + SureValve)* Attain Command™ + SureValve™ Guide catheter for left-heart delivery - K192712

**Predicate Device:** *(Attain Select II + SureValve)* Attain Select™ II + SureValve™ delivery catheter system - K192712

## Device Description

### Attain Command + SureValve Delivery System

The Attain Command + SureValve Delivery System outer guide catheters are designed to facilitate lead implantation in the left heart, via the coronary sinus and lead implantation in the right ventricle.

The Attain Command + SureValve Delivery System individual packs each contain one guide catheter with an integrated hemostasis valve (SureValve), up to two valve tools, and one dilator. The Attain Command + SureValve Delivery System is available in 12 models: 6250V-45S, 6250V-50S, 6250V-57S, 6250V-AM, 6250V-EH, 6250V-EHXL, 6250V-MB2, 6250V-MB2X, 6250V-MP, 6250V-MPR, 6250V-MPX, and 6250V-3D. Each model is different with respect to the guide catheter shape and length and dilator length.

The Attain Command + SureValve Delivery System kits each contain two outer guide catheters with an integrated hemostasis valve (SureValve), up to two valve tools, one dilator, one guide wire, and one slitter. The Attain Command + SureValve Delivery System kit is available in two models: 6250VC and 6250VS. With the exception of the two guide catheters, all system components packaged in each kit are identical. Each guide catheter model is different with respect to the guide catheter shape and length.

**Attain Select II + SureValve Delivery System**

The Attain Select II + SureValve delivery system is designed to facilitate left-heart lead delivery to a desired cardiac vein or right-heart lead delivery to the right ventricle. The delivery system includes a delivery catheter and an inner catheter. The delivery catheter aids in subselection and provides a pathway for the delivery of transvenous devices such as leads, inner catheters, and guide wires. It has a radiopaque flexible tip to facilitate viewing during fluoroscopy. The inner catheter supports the delivery catheter and aids in subselection. The inner catheter has a radiopaque tip and allows delivery of a guide wire or contrast solution. For left-heart use, the delivery catheter system is used with an outer guide catheter, which is the sheath used to gain coronary sinus access. Together, the catheters function as a telescoping system that can provide additional subselecting capabilities. For right-heart use, the delivery catheter system is used without an outer guide catheter.

The Attain Select II + SureValve delivery system consists of a delivery catheter with an integrated hemostasis valve (SureValve), an inner catheter, and up to two valve tools. The Attain Select II + SureValve delivery system is available in 8 models: 6248V-90, 6248V-90S, 6248V-90L, 6248V-130, 6248V-130L, 6248V-90P, 6248V-90SP, and 6248V-130P. The Attain Select II + SureValve inner catheter is identical for all configurations. Each model is different with respect to delivery catheter shape and length.

## Indications for Use

**Attain Command + SureValve Delivery System**

The delivery system is intended for introducing transvenous devices and leads into vessels of the left heart via the coronary sinus and into the right ventricle.

**Attain Select II + SureValve Delivery System**

The Attain Select II + SureValve delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus, left-heart venous anatomy, and the right

ventricle. For left heart use, the delivery catheter system is indicated for use with outer guide catheters. For right ventricle use, the delivery catheter system is indicated for use without an outer guide catheter.

## Technological Characteristics

The technology of the subject devices is identical to the respective predicates. The proposed labeling modifications subject of the 510(k) have no impact on the device design or materials, with the exception of the addition of new performance requirements related to lead delivery to the right ventricle. There are no changes to the Attain Select II + SureValve and Attain Command + SureValve design, physical characteristics, materials, packaging, or sterilization presented in this submission. Compared to the predicate devices, the proposed devices have updated labeling and instructions for use (IFU) to indicate that the catheters may also be used to deliver leads to the right ventricle. The subject devices have similar indications for use to the respective predicate devices. The intended use of the catheters, to introduce transvenous devices to the heart, remains the same.

When compared to the predicate devices (K192712), the subject Attain Select II + SureValve and subject Attain Command + SureValve presented in this submission have the same:

- Intended use
- Operating principle
- Design features
- Device functionality
- Biological safety
- Packaging materials
- Shelf life

The subject Attain Select II + SureValve and Attain Command + SureValve devices differ from the respective predicates in that the subject devices have indications for use updated to indicate that the catheters may also be used to deliver leads to the right ventricle.

## Substantial Equivalence and Summary of Studies

The indications for use differences between the subject and predicate devices have been evaluated with verification and validation testing. The labeling modifications to the subject device are supported through design verification and validation activities. All design verification and design validation activities were completed successfully. The subject devices are substantially equivalent to the specified predicate devices based on comparisons of the intended use, device functionality, and technological characteristics.

## Conclusion

The results of the above verification and validation testing met the specified acceptance criteria and did not raise new or different questions of safety or effectiveness. Therefore, the labeling modifications for the Attain Select II + SureValve and Attain Command + SureValve described in this submission result in a device that is substantially equivalent to the respective predicates.