June 30, 2026

Imricor Medical Systems, Inc.
Oksana Alswager
Sr. Regulatory Affairs Specialist
400 Gateway Blvd.
Burnsville, Minnesota 55337

Re: K261119
Trade/Device Name: NorthStar™ Mapping System, Vision-MR™ Diagnostic Catheter
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DRF
Dated: June 24, 2026
Received: June 25, 2026

Dear Oksana Alswager:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for: MARCO CANNELLA -S

Aneesh Deoras
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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K261119 |

Please provide the device trade name(s).

NorthStar™ Mapping System
Vision-MR™ Diagnostic Catheter

Please provide your Indications for Use below.

The NorthStar™ Mapping System is intended to aid interventional Cardiovascular Magnetic Resonance Imaging (iCMRI) procedures, including electrophysiology procedures, by providing a 3D environment in which MR images, devices, and procedure-related data are displayed.

The Vision-MR™ Diagnostic Catheter is intended for cardiac electrophysiological mapping (stimulating and recording) during electrophysiology procedures to diagnose arrhythmias and/or guide therapeutic decisions in adult and pediatric patients.

| | |
|---|---|
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |
| Please select the age group(s) for which the device(s) is to be used. | ☒ Neonates/Newborns (Birth to < 29 days old)<br>☒ Infants (29 days old to < 2 years old)<br>☒ Children (2 years old to < 12 years old)<br>☒ Adolescents (12 years old to < 22 years old)<br>☒ Adults (22 years old and greater) |

**Imricor Medical Systems, Inc.**

**NorthStar™ Mapping System, Vision-MR™ Diagnostic Catheter**

**K261119**

## 1. ADMINISTRATIVE INFORMATION

| | |
|---|---|
| Manufacturer: | Imricor Medical Systems, Inc.<br>400 Gateway Boulevard<br>Burnsville, MN 55337<br>USA<br>(952) 818-8400 |
| Official Contact: | Oksana Alswager, Senior Regulatory Specialist<br>Email: Oksana.alswager@imricor.com |
| Date Submitted: | June 24th, 2026 |

## 2. DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Proprietary Name: | NorthStar™ Mapping System<br>Vision-MR™ Diagnostic Catheter |
| Common Name: | Programmable Diagnostic Computer<br>Vision-MR Diagnostic Catheter |
| Classification Name: | Programmable Diagnostic Computer<br>Catheter, Electrode Recording, Or Probe, Electrode Recording |
| Classification Regulation: | 21 CFR 870.1425 (NorthStar Mapping System)<br>21 CFR 870.1220 (Vision-MR Diagnostic Catheter) |
| Device Class: | 2 |
| Product Code: | DQK (NorthStar Mapping System)<br>DRF (Vision-MR Diagnostic Catheter) |
| Review Panel: | Cardiovascular |

**3. PREDICATE DEVICE INFORMATION**

The devices within this submission is substantially equivalent in indications, intended use and design principles to the following legally marketed predicate devices:

| 510(k) | Predicate Device Name | Manufacturer Name |
|---|---|---|
| K252164 | NorthStar™ 3 Mapping System | Imricor Medical Systems, Inc. |
| K252794 | Vision-MR™ Diagnostic Catheter | Imricor Medical Systems, Inc. |

**4. INDICATIONS FOR USE**

NorthStar™ Mapping System is intended to aid interventional Cardiovascular Magnetic Resonance Imaging (iCMRI) procedures, including electrophysiology procedures, by providing a 3D environment in which MR images, devices, and procedure-related data are displayed.

The Vision-MR™ Diagnostic Catheter is intended for cardiac electrophysiological mapping (stimulating and recording) during electrophysiology procedures to diagnose arrhythmias and/or guide therapeutic decisions in adult and pediatric patients.

**5. DEVICE DESCRIPTION**

**NorthStar Mapping System** is a 3D mapping and navigation system for use in interventional Cardiovascular Magnetic Resonance Imaging (iCMRI) procedures (interventional cardiac procedures using periprocedural MR imaging). NorthStar provides a 3D environment in which real-time MR images of the anatomy, 3D representations of the anatomy, and device(s) are displayed. In addition, during electrophysiological (EP) procedures, NorthStar can display electroanatomical maps (voltage or activation) and/or therapy delivery information. These capabilities allow for procedure planning and guidance, and procedural therapy assessment.

NorthStar operating modes include:

- Real-time MR images
- 3D representations of anatomical structures (shells, volumes, etc.)
- Interventional device location
- Electroanatomical maps (EA Maps)
- Ablation points

The NorthStar system consists of a computer and application software, along with a monitor, mouse, and keyboard located in the control room. This system communicates with a compatible MR scanner computer and, during EP procedures, the Advantage-MR EP Recorder/Stimulator System (Advantage-MR).

The **Vision-MR Diagnostic Catheter** is an MR Conditional 9F (3.0 mm) catheter with a deflectable tip and two gold electrodes (1.3mm spacing): a 1.5mm tip electrode and a 1.4mm ring electrode. The catheter is designed to facilitate electrophysiological mapping of the heart (sensing and pacing) during cardiac electrophysiology procedures. The distal end of the catheter includes a receive coil to allow for MR tracking. The catheter is a sterile, single-use device.

The Vision-MR Diagnostic Catheter is a uni-directional deflectable catheter that is 115cm in length. The catheter handle incorporates a thumb control that deflects the catheter when pushed forward.

The Vision-MR Diagnostic Catheter must be used with the Advantage-MR™ EP Recorder/Stimulator System. Advantage-MR provides EP recording and cardiac stimulation capabilities and is the interface between the catheter and compatible medical devices, such as MR tracking systems. The Vision-MR Diagnostic Catheter interfaces with the Advantage-MR EP Recorder/Stimulator System via a sterile accessory cable (Vision-MR™ Diagnostic Cable 2.0).

## 6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The Subject devices, NorthStar Mapping System and the Vision-MR Diagnostic Catheter are both previously cleared devices that function together to support EP procedures and are included in this submission to expand the intended patient population to pediatric patients.

There are no changes to the design, intended use, materials, software, use environment, features, functions, or any other specifications of either device to support use in the pediatric population. The addition of pediatric use does not alter the compatibility between the Subject devices and does not introduce new or different modes of operation, and the fundamental operating principles remain the same.

Technological characteristics of the Subject devices remain unchanged, and as such the Subject devices do not raise different questions of safety and effectiveness. Therefore, the Subject devices are demonstrated to be substantially equivalent to their respective Predicate devices.

## 7. SUMMARY OF SUPPORTING EVIDENCE

This submission is supported by a technical analysis of real-world data demonstrating that MR-based imaging and visualization techniques can be performed safely in pediatric patients. These methods are consistent with the operating principles of the Subject devices. Review of the existing risk analysis confirmed that inclusion of pediatric use in labeling does not introduce new hazards or hazardous situations, and existing control measures remain effective.

The EO/ECH residual evaluation estimated weight and catheter insertion lengths for a wide range of pediatric patients and demonstrated that the estimated residuals are within the pediatric limits in ISO 10993-7 Amd:2019.

## 8. CONCLUSION

Overall, the information included in this submission demonstrates substantial equivalence of the Subject devices to the Predicates. The technological characteristics and operating principles remain unchanged. The technical analysis supports the safe and effective use of the Subject devices in pediatric patients. The inclusion of pediatric use in the labeling does not introduce new hazards or hazardous situations, does not change existing risks, and does not raise different questions of safety and effectiveness.

The conclusions drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as or better than the legally marketed predicate devices.