January 28, 2026

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

Re: K252164
Trade/Device Name: NorthStar™ Mapping System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: December 29, 2025
Received: December 29, 2025

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 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,

Aneesh S. Deoras -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.	K252164

Please provide the device trade name(s).

NorthStar™ Mapping System

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Imricor Medical Systems, Inc.

NorthStar™ Mapping System

1. ADMINISTRATIVE INFORMATION

Manufacturer:	Imricor Medical Systems, Inc. 400 Gateway Boulevard Burnsville, MN 55337 USA (952) 818-8400
Official Contact:	Oksana Alswager, Regulatory Affairs Specialist Email: oksana.alswager@imricor.com
Date Submitted:	July 9, 2025

2. DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	NorthStar™ Mapping System
Common Name:	Programmable Diagnostic Computer
Classification Name:	Programmable Diagnostic Computer
Classification Regulation:	21 CFR 870.1425
Device Class:	Class II
Product Code:	DQK
Review Panel:	Cardiovascular

3. PREDICATE DEVICE INFORMATION

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

510(k)	Predicate Device Name	Manufacturer Name
K231207	CARTO™ 3 EP Navigation System V8.0	Biosense Webster, Inc.

510(k)	Reference Device Name	Manufacturer Name
K111226	EndoScout Tracking System	Robin Medical, Inc.

4. INDICATIONS FOR USE

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.

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).

6. SUBSTANTIAL EQUIVALENCE & COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Substantial equivalence is claimed with the Predicate device. A Reference device is used to support the additional technology of tracking within the MR environment, which differ between the Subject and Predicate devices. Provided at the end of this section is a table which compares the Indications for Use Statements and technological characteristics of the Subject, Predicate and Reference devices.

Characteristic	Subject Device: NorthStar Mapping System	Predicate Device: CARTO™ 3 EP Navigation System (K231207)	Reference Device: EndoScout Tracking System (K111226)
Device Classification, Classification Name, and Product Code	Class II, Programmable Diagnostic Computer (21 CFR 870.1425), DQK	Equivalent	Not Applicable

Characteristic	Subject Device: NorthStar Mapping System	Predicate Device: CARTO™ 3 EP Navigation System (K231207)	Reference Device: EndoScout Tracking System (K111226)
Indications for Use	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.	Highly Similar	Not Applicable
Use Environment	Control Room of MRI Suite	Highly Similar	Highly Similar
Imaging Modality	Real-time MRI	Different	Highly Similar
User Group	Operating Room User Control Room User	Equivalent	Equivalent
Procedure Type	iCMRI procedures, including Electrophysiology procedures	Highly Similar	Similar
MRI Integration	Yes	Not Applicable	Highly Similar
Synchronized with MR Imaging	Yes	Not Applicable	Highly Similar
Utilize Data from Active Tracking Coils	Yes	Not Applicable	Highly Similar
Real-Time Localization	Yes (catheter navigation)	Equivalent	Highly Similar
Tracking Purpose	Real-time navigation of intracardiac devices during iCMRI procedures, including EP procedures	Equivalent	Similar
Type of Devices Tracked	Dynamic, navigating intravascular devices through cardiovascular system	Equivalent	Similar
Application	Interventional cardiovascular MRI procedures, including cardiac procedures	Highly Similar	Not Applicable
Shell Creation	MR imaging and Segmentation Tools	Similar	Not Applicable
Electroanatomical Mapping	Catheter-based anatomical mapping	Equivalent	Not Applicable

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Software verification and validation testing was completed on the Subject device demonstrating that the NorthStar Mapping System successfully performed as intended. Human factors testing confirmed safe use of the device under expected use conditions. All open issues from the verification and validation activities have been resolved. This testing supports the finding of substantial equivalence to the legally marketed Predicate device with a similar intended use.

8. CONCLUSION

Overall, the data included in this premarket notification demonstrates substantial equivalence of the Subject device to the Predicate device. The verification and validation testing included in this premarket notification demonstrates the NorthStar Mapping System performs as intended. This data supports the Subject device is substantially equivalent to the Predicate device.