January 8, 2026

Imricor Medical Systems, Inc.
Jordan Todd
Regulatory Specialist II
400 Gateway Boulevard
Burnsville, Minnesota 55337

Re: K252794
Trade/Device Name: Vision-MR™ Diagnostic Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: December 11, 2025
Received: December 11, 2025

Dear Jordan Todd:

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

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)*

K252794

Device Name

Vision-MR™ Diagnostic Catheter

Indications for Use *(Describe)*

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 patients age 18 years or older.

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.

510(k) Summary

Imricor Medical Systems, Inc.

Vision-MR™ Diagnostic Catheter

ADMINISTRATIVE INFORMATION

Manufacturer:	Imricor Medical Systems, Inc. 400 Gateway Boulevard Burnsville, MN 55337 USA (952) 818-8400
Official Contact:	Jordan Todd, Regulatory Specialist II Email: Jordan.todd@imricor.com
Date Submitted:	29AUG2025

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Vision-MR™ Diagnostic Catheter
Common Name:	Vision-MR Diagnostic Catheter
Classification Name:	Catheter, Electrode Recording, Or Probe, Electrode Recording
Classification Regulation:	21 CFR 870.1220
Device Class:	2
Product Code:	DRF - catheter, electrode recording, or probe, electrode recording
Review Panel:	Cardiovascular
Reviewing Branch:	CDRH

PREDICATE DEVICE INFORMATION

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

510(k)	Predicate Device Name	Manufacturer Name
K240366	EP XT™ Steerable Diagnostic Catheter	Boston Scientific Corporation

DEVICE DESCRIPTION

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).

INDICATIONS FOR USE

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 patients age 18 years or older.

EQUIVALENCE TO MARKETED DEVICE

The Subject Vision-MR Diagnostic Catheter is highly similar to the Predicate EP XT™ Steerable Diagnostic Catheter, manufactured by Boston Scientific. The indications for use, material construction, design, sterilization method, procedure type, patient population are all highly similar between the two devices. While the Subject device is primarily intended for use in the MR environment, it can also be used in a conventional fluoroscopy laboratory like the Predicate. Regardless of environment, they are both used by medical professionals for the purpose of stimulating (pacing) and recording during electrophysiology procedures. Both the Subject and Predicate devices are uni-directional diagnostic catheters, controlled using the same mechanism, comprised of flexible polymers which end in a tip comprised of precious metals.

Indications for Use Statement

The Subject and Predicate devices also are equivalent in their abilities to stimulate (pace) and record during electrophysiology procedure

Technological Characteristics

The indications for use, material construction, design, sterilization method, procedure type, patient population are all highly similar between the Predicate and Subject devices. While the Subject device is primarily intended for use in the MR environment, it can also be used in a conventional fluoroscopy laboratory like the Predicate.

NON-CLINICAL PERFORMANCE TEST DATA

The following performance data were provided in support of the substantial equivalence determination:

Bioburden and Endotoxin Testing

Bioburden and Endotoxin testing was performed to confirm levels of the devices were acceptable per the device nature of contact, duration, and efficacy of sterilization method.

Design Verification Testing

Design verification testing was performed to demonstrate that the devices, as manufactured, packaged and 2x EO sterilized, adhere to the requirements set forth in accordance with the applicable product specifications.

Testing was conducted at baseline (T=0) and 24 months real-time-aged to support the labeled shelf life.

Packaging Verification Testing

The Packaging Design Verification testing provides evidence that the catheter packaging configurations meet the predetermined design input specification and maintain sterility in conformance with ISO 11607-1.

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 Vision-MR Diagnostic Catheter performs as intended. The differences in the Subject device do not raise new questions of safety and effectiveness. This data supports the Subject device is substantially equivalent to the Predicate device.