FDA 510(k) Premarket Notification

K252794 Vision-MR™ Diagnostic Catheter

CLEARED

Jan 8, 2026
128 days to decision

K252794 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k252794/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Sep 2, 2025
Decision date	Jan 8, 2026
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Imricor Medical Systems, Inc.**
Location	Burnsville, MN, US
Contact	Jordan Todd
510(k) history	1 submissions · 1 cleared · 2026-2026