

K052908 INTRAREDX NIR IMAGING SYSTEM, MODEL MC-5Jun 23, 2006
252 days to decisionK052908 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k052908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Oct 14, 2005
Decision date	Jun 23, 2006
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infraredx, Inc.
Location	Burlington, MA, US
Contact	Nandini Murthy
510(k) history	11 submissions · 11 cleared · 2006-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052908/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026