

K063784 DYE MANAGEMENT SYSTEMApr 16, 2007
116 days to decisionK063784 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k063784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Dec 21, 2006
Decision date	Apr 16, 2007
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Icu Medical, Inc.
Location	Walker, MI, US
Contact	MARTIN MAIER
510(k) history	66 submissions · 65 cleared · 1984-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063784/> 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 June 28, 2026