

K083335 MODIFIED OMNIWAVE ENDOVASCULAR SYSTEMDec 15, 2008
33 days to decisionK083335 · Product code: **QEY** · Cardiovascular
Source: <https://www.510kdatabase.net/k083335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Nov 12, 2008
Decision date	Dec 15, 2008
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Omnisonics Medical Technologies
Location	Wilmington, MA, US
Contact	ANNE M KULIS
510(k) history	8 submissions · 8 cleared · 1999-2008

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