

K082646 OPTIMUS 0.035 PTA BALLOON DILATATION CATHETER

Nov 3, 2008
53 days to decision

K082646 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k082646/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 11, 2008
Decision date	Nov 3, 2008
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Usci Ireland
Location	North Reading, MA, US
Contact	MAUREEN O'CONNELL
510(k) history	2 submissions · 2 cleared · 2007-2008

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k082646/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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