

K111738 CHOCOLATE PTA BALLOON CATHETER (OVER THE WIRE) GUIDE WIRE (0.014 AND 0.018)

Dec 14, 2011
176 days to decision

K111738 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k111738/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 21, 2011
Decision date	Dec 14, 2011
Days to decision	176 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Trireme Medical, Inc.
Location	Pleasanton, CA, US
Contact	SHIVA ARDAKAMI
510(k) history	12 submissions · 12 cleared · 2010-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k111738/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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