

K112281 GLIDERXTREME PTA BALLON CATHETER (OVER THE WIRE) 0.018 GUIDE WIRE 6100-XXXX, 6100CB-XXXX

Aug 17, 2011
8 days to decision

K112281 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k112281/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 9, 2011
Decision date	Aug 17, 2011
Days to decision	8 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k112281/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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