

**K120533 BIGBOSS CATHETERS MANTATAY CATHETER
MANTARAY GUIDEWIRES**May 22, 2012
90 days to decisionK120533 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k120533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Feb 22, 2012
Decision date	May 22, 2012
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bridgepoint Medical
Location	Orinda, CA, US
Contact	JILL MUNSINGER
510(k) history	14 submissions · 14 cleared · 2008-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120533/> 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 15, 2026