

K112335 BANTAM CATHETER (280MM BALLOON LENGTHS)Oct 12, 2011
61 days to decisionK112335 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k112335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 12, 2011
Decision date	Oct 12, 2011
Days to decision	61 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	ClearStream Technologies , Ltd.
Location	Austin, TX, US
Contact	FIONA NI MHULLAIN
510(k) history	7 submissions · 7 cleared · 2008-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112335/> 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 18, 2026