

**K112327 SENSATION(TM) PLUS 8FR. 50CC INTRA-AORTIC
BALLOON CATHETER AND ACCESSORIES**Sep 9, 2011
28 days to decisionK112327 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k112327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Aug 12, 2011
Decision date	Sep 9, 2011
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiac Assist, Maquet Cardiovascular, LLC
Location	Manwah, NJ, US
Contact	HELDER A SOUSA
510(k) history	2 submissions · 2 cleared · 2011-2011

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