FDA 510(k) Premarket Notification

K112372 CARDIOSAVE HYBRID INTRA-AORTIC BALLOON PUMP

CLEARED

Sep 15, 2011
29 days to decision

K112372 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k112372/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Aug 17, 2011
Decision date	Sep 15, 2011
Days to decision	29 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