

K163608 HAART 300 Aortic Annuloplasty Device 19mm, HAART 300 Aortic Annuloplasty Device 21mm, HAART 300 Aortic Annuloplasty Device 23mm, HAART 300 Aortic Annuloplasty Device 25mmMar 21, 2017
90 days to decisionK163608 · Product code: **PST** · Cardiovascular
Source: <https://www.510kdatabase.net/k163608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aortic Annuloplasty Ring (PST)
Date received	Dec 21, 2016
Decision date	Mar 21, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biostable Science & Engineering, Inc.
Location	Austin, TX, US
Contact	Julie Thomas
510(k) history	2 submissions · 2 cleared · 2017-2017

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