

**K171431 HAART 200 Aortic Annuloplasty Device 19mm, HAART 200 Aortic Annuloplasty Device 21mm, HAART 200 Aortic Annuloplasty Device 23mm, HAART 200 Aortic Annuloplasty Device 25mm**Aug 10, 2017  
87 days to decisionK171431 · Product code: **PST** · Cardiovascular  
Source: <https://www.510kdatabase.net/k171431/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aortic Annuloplasty Ring (PST)
Date received	May 15, 2017
Decision date	Aug 10, 2017
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171431/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026