CLEARED

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 decision

K171431 · Product code: **PST** · Cardiovascular
Source: https://www.510kdatabase.net/k171431/

SUBMISSION DETAILS

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

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