

K092876 SJM ATTUNE ANNULOPLASTY RINGOct 16, 2009
28 days to decisionK092876 · Product code: **KRH** · CardiovascularSource: <https://www.510kdatabase.net/k092876/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Ring, Annuloplasty (KRH) |
| Date received | Sep 18, 2009 |
| Decision date | Oct 16, 2009 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------------------|
| Company | St Jude Medical |
| Location | Minnetonka, MN, US |
| Contact | THOMAS TADEMACHER |
| Website | http://www.sjm.com/ |
| 510(k) history | 105 submissions · 105 cleared · 2000-2018 |

St Jude Medical was a global medical device company headquartered in Little Canada, Minnesota. The company operated more than 20 principal facilities worldwide and sold products in over 100 countries. St Jude Medical received FDA 510(k) clearances from total submissions between 2000 and 2018. The company's regulatory focus centered on Cardiovascular devices, which represented 91% of all submissions. Notable cleared products include cardiac mapping systems, pacing catheters, and mobile cardiac applications. Now part of Abbott Laboratories following its acquisition in Janua...