

**K180411 MEMO 4D**Mar 16, 2018  
29 days to decisionK180411 · Product code: **KRH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180411/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ring, Annuloplasty (KRH)
Date received	Feb 15, 2018
Decision date	Mar 16, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sorin Group Italia S.R.L.</b>
Location	Mirandola, IT
Contact	Mauro Ercolani
510(k) history	61 submissions · 61 cleared · 1995-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180411/> 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 May 30, 2026