

**K121319 ZIO PATCH**Jul 18, 2012  
77 days to decisionK121319 · Product code: **DSH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k121319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	May 2, 2012
Decision date	Jul 18, 2012
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>iRhythm Technologies, Inc.</b>
Location	San Francisco, CA, US
Contact	MICHAEL RIGHTER
510(k) history	18 submissions · 18 cleared · 2008-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121319/> 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 14, 2026