

**K162571 Bioflux Software**Oct 13, 2016  
28 days to decisionK162571 · Product code: **DSH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k162571/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 15, 2016
Decision date	Oct 13, 2016
Days to decision	28 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biotricity, Inc.</b>
Location	Toronto, CA
Contact	Tom Elias
510(k) history	2 submissions · 2 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162571/> 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 31, 2026