

**K183634 Stasis Monitoring System**Apr 17, 2019  
112 days to decisionK183634 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k183634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 26, 2018
Decision date	Apr 17, 2019
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stasis Labs, Inc.</b>
Location	Los Angeles, CA, US
Contact	Derek Nielsen
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>510konsult, LLC</b>
Contact	Eric Eggers

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183634/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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