

**K183176 Endotoxin Activity Assay (EAA)**Mar 12, 2019  
116 days to decisionK183176 · Product code: **NGS** · Microbiology  
Source: <https://www.510kdatabase.net/k183176/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Endotoxin Activity, Chemiluminescent (NGS)
Date received	Nov 16, 2018
Decision date	Mar 12, 2019
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Spectral Medical, Inc.</b>
Location	Toronto, CA
Contact	Danijela Domljanovic
510(k) history	2 submissions · 2 cleared · 2017-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183176/> 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 28, 2026