

**K152955 Great Basin Shiga Toxin Direct Test**Mar 22, 2016  
167 days to decisionK152955 · Product code: **PCH** · Microbiology  
Source: <https://www.510kdatabase.net/k152955/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Oct 7, 2015
Decision date	Mar 22, 2016
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Great Basin Scientific, Inc.</b>
Location	Salt Lake City, UT, US
Contact	Chuck Owen
510(k) history	4 submissions · 4 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152955/> 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 1, 2026