

**K200986 OPTI® B-Lac Cassette**Aug 2, 2021  
474 days to decisionK200986 · Product code: **CHL** · Chemistry  
Source: <https://www.510kdatabase.net/k200986/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Apr 15, 2020
Decision date	Aug 2, 2021
Days to decision	474 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Opti Medical Systems, Inc.</b>
Location	Roswell, GA, US
Contact	Theron Gober
510(k) history	3 submissions · 3 cleared · 2011-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200986/> 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 26, 2026