

**K162042 OptiScanner 5000 Glucose Monitoring System**Oct 16, 2017  
448 days to decisionK162042 · Product code: **LZF** · Chemistry  
Source: <https://www.510kdatabase.net/k162042/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Analytical Sampling (LZF)
Date received	Jul 25, 2016
Decision date	Oct 16, 2017
Days to decision	448 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Optiscan Biomedical Corp.</b>
Location	Hayward, CA, US
Contact	DON WEBBER
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162042/> 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