

K192785 OptiScanner® 5000 Glucose Monitoring SystemFeb 5, 2020
128 days to decisionK192785 · Product code: **LZF** · Chemistry
Source: <https://www.510kdatabase.net/k192785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Analytical Sampling (LZF)
Date received	Sep 30, 2019
Decision date	Feb 5, 2020
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Optiscan Biomedical Corporation
Location	Hayward, CA, US
Contact	Charles Zimlik
510(k) history	1 submissions · 1 cleared · 2020-2020

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