

K242997 MY01 Continuous Compartmental Pressure MonitorMar 13, 2025
168 days to decisionK242997 · Product code: **LXC** · Orthopedic
Source: <https://www.510kdatabase.net/k242997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intracompartmental (LXC)
Date received	Sep 26, 2024
Decision date	Mar 13, 2025
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MY01, Inc.
Location	Montreal, CA
Contact	Olivier Bataille
510(k) history	6 submissions · 6 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242997/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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