FDA 510(k) Premarket Notification

K251900 MY01 Continuous Compartmental Pressure Monitor

CLEARED

Jan 16, 2026
210 days to decision

K251900 · Product code: **LXC** · Orthopedic
Source: https://www.510kdatabase.net/k251900/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intracompartmental (LXC)
Date received	Jun 20, 2025
Decision date	Jan 16, 2026
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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