

K192629 SpinalyticsDec 21, 2019
89 days to decisionK192629 · Product code: **LXM** · Neurology
Source: <https://www.510kdatabase.net/k192629/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manipulator, Plunger-like Joint (LXM)
Date received	Sep 23, 2019
Decision date	Dec 21, 2019
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Optima Health Solutions International Corp.
Location	Vancouver, CA
Contact	Farhad Ghani
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Diane Sudduth

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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