

K222698 CUVIS-spineOct 7, 2022
30 days to decisionK222698 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k222698/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 7, 2022
Decision date	Oct 7, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Curexo, Inc.
Location	Seoul, KR
Contact	Jungeun Park
510(k) history	4 submissions · 4 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Bt Solutions, Inc.
Contact	Do Hyun Kim

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

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