

**K201569 CUVIS-spine**May 19, 2021  
342 days to decisionK201569 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k201569/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 11, 2020
Decision date	May 19, 2021
Days to decision	342 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bt Solutions, Inc.</b>
Contact	Do Hyun Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201569/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 25, 2026