FDA 510(k) Premarket Notification

K201569 CUVIS-spine

CLEARED

May 19, 2021
342 days to decision

K201569 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k201569/

SUBMISSION DETAILS

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

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