FDA 510(k) Premarket Notification

K222698 CUVIS-spine

CLEARED

Oct 7, 2022
30 days to decision

K222698 · 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