FDA 510(k) Premarket Notification

CLEARED

K243739 AxCess® Expandable Interbody System

Jan 24, 2025
51 days to decision

K243739 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k243739/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 4, 2024
Decision date	Jan 24, 2025
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Elliquence, LLC**
Location	Shelton, CT, US
Contact	Paul Buhrke, IV
510(k) history	8 submissions · 8 cleared · 2010-2025

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Nathan Wright

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