FDA 510(k) Premarket Notification

K221325 CONDUIT Lateral Switch Plate

CLEARED

Aug 25, 2022
111 days to decision

K221325 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k221325/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 6, 2022
Decision date	Aug 25, 2022
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medos International SARL**
Location	Raynham, MA, US
Contact	LiJuan He
510(k) history	96 submissions · 96 cleared · 2010-2026

REGULATORY CONSULTANT

Consulting firm	**Depuy Spine**
Contact	LiJuan He

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