FDA 510(k) Premarket Notification

K210728 CONDUIT Instruments

CLEARED

May 6, 2021
56 days to decision

K210728 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k210728/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 11, 2021
Decision date	May 6, 2021
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Depuy Spine**
Contact	Christine Cahillane

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