FDA 510(k) Premarket Notification

K212823 DePuy CONDUIT LLIF Angled Inserters

CLEARED

Nov 1, 2021
59 days to decision

K212823 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k212823/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 3, 2021
Decision date	Nov 1, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Enztec Limited**
Location	Middleton, NZ
Contact	Claire Mai
510(k) history	5 submissions · 5 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Meredith Lee May

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