FDA 510(k) Premarket Notification

K200551 MectaLIF Transforaminal TiPEEK

CLEARED

Feb 12, 2021
346 days to decision

K200551 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k200551/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 3, 2020
Decision date	Feb 12, 2021
Days to decision	346 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medacta Inernational SA**
Location	Castel San Pietro (Ch), CH
Contact	Stefano Baj
510(k) history	4 submissions · 4 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	**Medacta USA**
Contact	Chris Lussier

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