FDA 510(k) Premarket Notification

K200048 MectaLIF Anterior Simple

CLEARED

Mar 9, 2020
60 days to decision

K200048 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k200048/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 9, 2020
Decision date	Mar 9, 2020
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medacta International S.A.**
Location	Castel San Pietro, CH
Contact	Stefano Baj
Website	https://www.medacta.com
510(k) history	164 submissions · 164 cleared · 2008-2026