FDA 510(k) Premarket Notification

K181970 MectaLIF Posterior Extension

CLEARED

Dec 4, 2018
133 days to decision

K181970 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181970/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 24, 2018
Decision date	Dec 4, 2018
Days to decision	133 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