FDA 510(k) Premarket Notification

K200316 UNiD IB3D ALIF

CLEARED

Oct 30, 2020
266 days to decision

K200316 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k200316/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 7, 2020
Decision date	Oct 30, 2020
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medicrea International SA**
Location	Neyron, FR
Contact	David Ryan
510(k) history	25 submissions · 25 cleared · 2015-2022