FDA 510(k) Premarket Notification

K190092 UNiD Patient specific 3D printed TLIF cage

CLEARED

May 8, 2019
110 days to decision

K190092 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k190092/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 18, 2019
Decision date	May 8, 2019
Days to decision	110 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