FDA 510(k) Premarket Notification

K241164 IB3D™ PL Spinal System

CLEARED

Sep 6, 2024
133 days to decision

K241164 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k241164/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 26, 2024
Decision date	Sep 6, 2024
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medicrea International S.A.S. (Medtronic)**
Location	Rillieux-La-Pape, FR
Contact	Cecile Humbert
510(k) history	3 submissions · 3 cleared · 2024-2025