

K253577 IB3D™ PL Spinal System (A24000000 / IB3D Universal Implant Inserter)Dec 19, 2025
32 days to decisionK253577 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k253577/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 17, 2025
Decision date	Dec 19, 2025
Days to decision	32 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	Gautier Liegeon
510(k) history	3 submissions · 3 cleared · 2024-2025

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