

K222028 IdentiTi™ Porous Ti Interbody System, IdentiTi™ NanoTec™ Interbody System, Transcend™ PEEK Interbody System, Transcend™ NanoTec™ Interbody System, IdentiTi™ ALIF Standalone Interbody System, IdentiTi™ NanoTec™ ALIF Standalone Interbody System

Oct 7, 2022
88 days to decision

K222028 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k222028/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 11, 2022
Decision date	Oct 7, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alphatec Spine
Location	Carlsnad, CA, US
Contact	Neha Mohindroo
510(k) history	6 submissions · 6 cleared · 2016-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k222028/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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