FDA 510(k) Premarket Notification

K241375 IdentiTi Porous Ti Interbody System

CLEARED

Feb 3, 2025
264 days to decision

K241375 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k241375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 15, 2024
Decision date	Feb 3, 2025
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	IdentiTi NanoTec Interbody System; IdentiTi Cervical Porous Ti Interbody System; IdentiTi NanoTec Cervical Interbody System; IdentiTi Cervical Standalone Interbody System; IdentiTi NanoTec Cervical Standalone Interbody System; IdentiTi ALIF Standalone Interbody System; IdentiTi NanoTec ALIF Standalone Interbody System; Transcend PEEK Interbody System; Transcend NanoTec Interbody System; Transcend Cervical PEEK Interbody System; Transcend NanoTec Cer

APPLICANT

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