FDA 510(k) Premarket Notification

K122317 TETRIS II

CLEARED

Aug 29, 2012
28 days to decision

K122317 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k122317/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 1, 2012
Decision date	Aug 29, 2012
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Signus Medizintechnik GmbH**
Location	Minneapolis, MN, US
Contact	KAREN E WARDEN
510(k) history	23 submissions · 22 cleared · 1999-2025