

**K080615 ENDOSKELETON TA INTERBODY FUSION DEVICE
(IBD)**Jun 17, 2008
105 days to decisionK080615 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k080615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 4, 2008
Decision date	Jun 17, 2008
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Titan Spine, LLC
Location	Mequon, WI, US
Contact	KEVIN GEMAS
510(k) history	14 submissions · 14 cleared · 2008-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080615/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026