

K183064 TxTi IBF SystemJun 28, 2019
235 days to decisionK183064 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k183064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 5, 2018
Decision date	Jun 28, 2019
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovasis, Inc.
Location	Salt Lake City, UT, US
Contact	Marshall McCarty
510(k) history	33 submissions · 32 cleared · 2004-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183064/> 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 June 28, 2026