

K201614 TxTiHA IBF System, AxTiHA Stand-Alone ALIF SystemJul 15, 2020
30 days to decisionK201614 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k201614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 15, 2020
Decision date	Jul 15, 2020
Days to decision	30 days
Third-party review	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

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