

**K180078 Px PEEK IBF System, Px HA PEEK IBF System, TxHA
PEEK IBF System**Apr 17, 2018
97 days to decisionK180078 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k180078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 10, 2018
Decision date	Apr 17, 2018
Days to decision	97 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180078/>; 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