

**K192718 Fortilink Interbody Fusion Device (IBF) with
TETRAfuse 3D Technology**Dec 20, 2019
84 days to decisionK192718 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k192718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 27, 2019
Decision date	Dec 20, 2019
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pioneer Surgical Technology, Inc. (Dba Rti Surgical, Inc.)
Location	Marquette, MI, US
Contact	Linda Busklein
510(k) history	15 submissions · 15 cleared · 2015-2020

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