FDA 510(k) Premarket Notification

CLEARED

K190498 Fortilink® IBF System with TETRAfuse®3D Technology, include the following designs: Fortilink®-TS IBF System, Fortilink®-L I BF System, Fortilink®-C IBF System

Jul 5, 2019
127 days to decision

K190498 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k190498/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 28, 2019
Decision date	Jul 5, 2019
Days to decision	127 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	Kristina Hall
510(k) history	15 submissions · 15 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	**Musculoskeletal Clinical Regulatory Advisers, LLC**
Contact	Justin Eggleton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov