FDA 510(k) Premarket Notification

CLEARED

K172343 Fortilink® Interbody Fusion (IBF) System with TETRAfuse® 3D Technology

Oct 23, 2017
82 days to decision

K172343 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k172343/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 2, 2017
Decision date	Oct 23, 2017
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rti Surgical, Inc.**
Location	Alachua, FL, US
Contact	Diana Taylor
510(k) history	7 submissions · 7 cleared · 2014-2025