FDA 510(k) Premarket Notification

CLEARED

K171689 ARTiC-L 3D Ti Spinal System with TiONIC Technology, ARTiC-XL 3D Ti Spinal System with TiONIC Technology

Oct 5, 2017
120 days to decision

K171689 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k171689/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 7, 2017
Decision date	Oct 5, 2017
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek USA, Inc.**
Location	Memphis, TN, US
Contact	Kelly Anglin
510(k) history	170 submissions · 159 cleared · 2000-2026