CLEARED

Mar 23, 2020
264 days to decision

K191788 CAPSTONE Spinal System, CLYDESDALE PTC Spinal System, CRESCENT Spinal System, CRESCENT Spinal System Titanium, DIVERGENCE-L Anterior/Oblique Lumbar Fusion System

K191788 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k191788/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 3, 2019
Decision date	Mar 23, 2020
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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