CLEARED

Jan 22, 2020
132 days to decision

K192502 Anatomic PEEK™ Cervical Fusion System, Anatomic PEEK™ PTC Cervical Fusion System, Capstone™ Spinal System, Capstone PTC™ Spinal System, Capstone Control™ Spinal System, Capstone Control PTC™ Spinal System, Clydesdale™ Spinal System, Clydesdale PTC™ Spinal System, Cornerstone™ PSR Cervical Fusion System, Crescent™ Spinal System, Crescent™ Spinal System Titanium, Divergence™ Anterior Cervical Fusion System (For Stand-Alone Interbody Device Only), Divergence-L™ Anterior/Oblique Lumbar Fus

K192502 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k192502/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 12, 2019
Decision date	Jan 22, 2020
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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