FDA 510(k) Premarket Notification

CLEARED

K171107 CAPSTONE CONTROL Spinal System, CAPSTONE CONTROL PTC Spinal System

Sep 26, 2017
165 days to decision

K171107 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k171107/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 14, 2017
Decision date	Sep 26, 2017
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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