FDA 510(k) Premarket Notification

CLEARED

K151128 CAPSTONE Spinal System, CLYDESDALE Spinal System

Aug 6, 2015
100 days to decision

K151128 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k151128/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 28, 2015
Decision date	Aug 6, 2015
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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