

K133205 CAPSTONE PTC SPINAL SYSTEM, CLYDESDALE PTC SPINAL SYSTEMMar 13, 2014
146 days to decisionK133205 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k133205/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 18, 2013
Decision date	Mar 13, 2014
Days to decision	146 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133205/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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