

K133653 ANATOMIC PEEK PTC CERVICAL FUSION SYSTEMApr 28, 2014
152 days to decisionK133653 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k133653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 27, 2013
Decision date	Apr 28, 2014
Days to decision	152 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

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