FDA 510(k) Premarket Notification

K143450 Ackermann Intervertebral Body Fusion Device

CLEARED

Sep 16, 2015
288 days to decision

K143450 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k143450/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Dec 2, 2014
Decision date	Sep 16, 2015
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ackermann Instrumente GmbH**
Location	Chesterland, OH, US
Contact	Rolf Ackermann
510(k) history	3 submissions · 3 cleared · 1998-2015