FDA 510(k) Premarket Notification

K161809 ShurFit CpTi-HA ACIF Interbody Fusion System

CLEARED

Dec 6, 2016
158 days to decision

K161809 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k161809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 1, 2016
Decision date	Dec 6, 2016
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Precision Spine, Inc.**
Location	Pear, MS, US
Contact	Michael C. Dawson
510(k) history	24 submissions · 24 cleared · 2014-2025