FDA 510(k) Premarket Notification

K160222 OIC Cervical PEEK Spacer

CLEARED

Dec 7, 2016
313 days to decision

K160222 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k160222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jan 29, 2016
Decision date	Dec 7, 2016
Days to decision	313 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**The Orthopaedic Implant Company**
Location	Greenwood Village, CO, US
Contact	DOUGLAS FULTON
510(k) history	5 submissions · 5 cleared · 2012-2024