FDA 510(k) Premarket Notification

K162241 TITAN 3-D™ Wedge System

CLEARED

Apr 3, 2017
236 days to decision

K162241 · Product code: **PLF** · Orthopedic
Source: https://www.510kdatabase.net/k162241/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Wedge (PLF)
Date received	Aug 10, 2016
Decision date	Apr 3, 2017
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Paragon 28**
Location	Chesterland, OH, US
Contact	Frank S. Bono
510(k) history	7 submissions · 7 cleared · 2014-2018