FDA 510(k) Premarket Notification

K131810 OSSEUS BLACK DIAMOND PEDICLE SCREW SYSTEM

CLEARED

Aug 8, 2013
50 days to decision

K131810 · Product code: **MNH** · Orthopedic
Source: https://www.510kdatabase.net/k131810/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jun 19, 2013
Decision date	Aug 8, 2013
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osseus Fusion Systems, LLC**
Location	Round Rock, TX, US
Contact	J.D. WEBB
510(k) history	5 submissions · 5 cleared · 2013-2022