FDA 510(k) Premarket Notification

K140678 COSMOLOCK PEDICLE SCREW SYSTEM

CLEARED

Jun 19, 2014
93 days to decision

K140678 · Product code: **MNH** · Orthopedic
Source: https://www.510kdatabase.net/k140678/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Mar 18, 2014
Decision date	Jun 19, 2014
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kalitec Direct, LLC**
Location	Round Rock, TX, US
Contact	J.D. WEBB
510(k) history	9 submissions · 9 cleared · 2011-2018