FDA 510(k) Premarket Notification

K153720 ENZA Zero-Profile Anterior Interbody Fusion

CLEARED

May 3, 2016
127 days to decision

K153720 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k153720/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Dec 28, 2015
Decision date	May 3, 2016
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Camber Spine Technologies**
Location	Newtown Square, PA, US
Contact	Michael Black
510(k) history	17 submissions · 17 cleared · 2013-2024