FDA 510(k) Premarket Notification

K163386 Keos Lumbar IBFD

CLEARED

Apr 10, 2017
129 days to decision

K163386 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k163386/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 2, 2016
Decision date	Apr 10, 2017
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Keos**
Location	Lancaster, PA, US
Contact	Mark F Schenk
Website	http://www.keos.org/
510(k) history	4 submissions · 4 cleared · 2016-2022

Keos is a medical device company with a manufacturing facility in Lancaster, US. The company specializes in Orthopedic devices for spinal fusion and interbody fusion applications. Keos received FDA 510(k) clearances from total submissions between 2016 and 2022. The company's regulatory portfolio is entirely focused on Orthopedic devices, including anterior cervical and lumbar interbody fusion systems. Keos is currently inactive with no clearances recorded in the past five years and should be treated as a historical regulatory record. For detailed information on cleared de...