

K160631 Keos Lumbar IBFDJul 15, 2016
130 days to decisionK160631 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k160631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 7, 2016
Decision date	Jul 15, 2016
Days to decision	130 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...
