

K212450 Keos Anterior Cervical Interbody Fusion Device System

Jun 6, 2022
305 days to decisionK212450 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k212450/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 5, 2021
Decision date	Jun 6, 2022
Days to decision	305 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Keos
Location	Lancaster, PA, US
Contact	Scott Peterson
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...

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Maris Garner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k212450/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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