FDA 510(k) Premarket Notification

K221172 FOCUS Interbody System

CLEARED

Oct 14, 2022
172 days to decision

K221172 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k221172/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 25, 2022
Decision date	Oct 14, 2022
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oc Medical Devices**
Location	Savannah, GA, US
Contact	Jack Mathews
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting, Inc.**
Contact	Karen E. Warden

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