FDA 510(k) Premarket Notification

K233694 Meridian Interbody System

CLEARED

Jan 12, 2024
56 days to decision

K233694 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k233694/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 17, 2023
Decision date	Jan 12, 2024
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	WaveForm A Interbody System

APPLICANT

Company	**SeaSpine Orthopedics Corporation**
Location	Carlsbad, CA, US
Contact	Jesse Albright
510(k) history	66 submissions · 66 cleared · 2016-2025