FDA 510(k) Premarket Notification

K192006 SIRION Lateral Lumbar Interbody System

CLEARED

Apr 2, 2020
248 days to decision

K192006 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k192006/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 29, 2019
Decision date	Apr 2, 2020
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Astura Medical, LLC**
Location	Carlsbad, CA, US
Contact	Parker Kelch
510(k) history	8 submissions · 8 cleared · 2018-2021