

K202495 SIRION Lateral Lumbar Interbody FusionJan 6, 2021
128 days to decisionK202495 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k202495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 31, 2020
Decision date	Jan 6, 2021
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202495/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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