

K182877 HALF DOME Posterior Lumbar Interbody SystemMay 3, 2019
200 days to decisionK182877 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k182877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 15, 2018
Decision date	May 3, 2019
Days to decision	200 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

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