

K152512 Half Dome Posterior Lumbar Interbody SystemJan 28, 2016
148 days to decisionK152512 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k152512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 2, 2015
Decision date	Jan 28, 2016
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Astura Medical
Location	Carlsbad, CA, US
Contact	Thomas Astura
510(k) history	21 submissions · 21 cleared · 2016-2026

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