

K163481 HALF DOME Posterior Lumbar Interbody SystemMay 3, 2017
142 days to decisionK163481 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k163481/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 12, 2016
Decision date	May 3, 2017
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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