

K172947 HALF DOME Posterior Lumbar Interbody SystemApr 18, 2018
204 days to decisionK172947 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k172947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 26, 2017
Decision date	Apr 18, 2018
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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