

K150395 Omega LIF SystemAug 10, 2015
173 days to decisionK150395 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k150395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 18, 2015
Decision date	Aug 10, 2015
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Amendia, Inc.
Location	Apple Valley, MN, US
Contact	Bruce Hooper
510(k) history	16 submissions · 16 cleared · 2009-2016

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