

K110177 HELENA SYSTEMApr 21, 2011
90 days to decisionK110177 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k110177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 21, 2011
Decision date	Apr 21, 2011
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Royal Oak Medical Devices
Location	Bloomfield Hills, MI, US
Contact	MATTHEW KROLL
510(k) history	2 submissions · 2 cleared · 2011-2011

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