

K112429 GIZA(R) VERTEBRAL BODY REPLACEMENTJan 26, 2012
156 days to decisionK112429 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k112429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Aug 23, 2011
Decision date	Jan 26, 2012
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eden Spine, LLC
Location	Apple Valley, MN, US
Contact	RICH JANSEN
510(k) history	2 submissions · 2 cleared · 2012-2016

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