FDA 510(k) Premarket Notification

K110177 HELENA SYSTEM

CLEARED

Apr 21, 2011
90 days to decision

K110177 · 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