

K102438 PRIMALOK FACET FIXATION SYSTEMSep 30, 2010
35 days to decisionK102438 · Product code: **MRW** · Orthopedic
Source: <https://www.510kdatabase.net/k102438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Aug 26, 2010
Decision date	Sep 30, 2010
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteomed LP
Location	Addison, TX, US
Contact	KAREN E WARDEN
510(k) history	29 submissions · 29 cleared · 2003-2015

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