FDA 510(k) Premarket Notification

K073515 TRANS1 FACET SCREW

CLEARED

Mar 11, 2008
88 days to decision

K073515 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k073515/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Dec 14, 2007
Decision date	Mar 11, 2008
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Trans1 Incorporated**
Location	Wilmington, NC, US
Contact	WILLIAM JACKSON
510(k) history	9 submissions · 9 cleared · 2005-2012