FDA 510(k) Premarket Notification

K083567 GII SPINAL FIXATION SYSTEM, GII-TI-POLY AXIAL SCREW

CLEARED

Sep 14, 2009
285 days to decision

K083567 · Product code: **MNH** · Orthopedic
Source: https://www.510kdatabase.net/k083567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Dec 3, 2008
Decision date	Sep 14, 2009
Days to decision	285 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Co-Ligne AG**
Location	Montreal, CA
Contact	DAVID W SCHLERF
510(k) history	4 submissions · 4 cleared · 2004-2009