

K161332 NILE Proximal Fixation Spinal SystemApr 5, 2017
328 days to decisionK161332 · Product code: **OWI** · Orthopedic
Source: <https://www.510kdatabase.net/k161332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	May 12, 2016
Decision date	Apr 5, 2017
Days to decision	328 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	K2m, Inc.
Location	Leesburg, VA, US
Contact	NANCY GIEZEN
510(k) history	100 submissions · 97 cleared · 2007-2026

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