

K143350 Nile Alternative FixationFeb 25, 2015
93 days to decisionK143350 · Product code: **OWI** · Orthopedic
Source: <https://www.510kdatabase.net/k143350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Nov 24, 2014
Decision date	Feb 25, 2015
Days to decision	93 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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