

**K132395 LIGAPASS**Dec 6, 2013  
127 days to decisionK132395 · Product code: **OWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k132395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Aug 1, 2013
Decision date	Dec 6, 2013
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea International</b>
Location	Round Rock, TX, US
Contact	AUDREY VION
510(k) history	17 submissions · 16 cleared · 2011-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132395/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026