

**K213659 LigaPASS™ 2.0 Ligament Augmentation System**May 24, 2022  
186 days to decisionK213659 · Product code: **OWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k213659/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Nov 19, 2021
Decision date	May 24, 2022
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea International SA</b>
Location	Neyron, FR
Contact	Teal Bjoraker
510(k) history	25 submissions · 25 cleared · 2015-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Justin Eggleton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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