

**K212391 MCI-Neuro Fixation System**Oct 21, 2022  
445 days to decisionK212391 · Product code: **GWO** · Neurology  
Source: <https://www.510kdatabase.net/k212391/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Aug 2, 2021
Decision date	Oct 21, 2022
Days to decision	445 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mci Medical Concept Innovation, Inc.</b>
Location	Sunrise, FL, US
Contact	Carlos Lacerda
510(k) history	2 submissions · 2 cleared · 2019-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Passarini Regulatory Affairs/ PR Servicos</b>
Contact	Graziela Brum

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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