

**K231920 Longeviti ClearFit OTS Cranial Implant**Nov 9, 2023  
133 days to decisionK231920 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k231920/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Jun 29, 2023
Decision date	Nov 9, 2023
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Longeviti Neuro Solutions, LLC</b>
Location	Hunt Valley, MD, US
Contact	Jesse Christopher
510(k) history	8 submissions · 8 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231920/> 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 25, 2026