

**K121755 CUSTOM CRANIOFACIAL IMPLANT (CCI)**Sep 25, 2012  
102 days to decisionK121755 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k121755/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Jun 15, 2012
Decision date	Sep 25, 2012
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kelyniam Global, Inc.</b>
Location	New Britain, CT, US
Contact	NICHOLAS BREAULT
510(k) history	4 submissions · 4 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121755/> 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 26, 2026