

**K151692 BioArchitects Patient Specific Cranial/Craniofacial Plate**Nov 20, 2015  
150 days to decisionK151692 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k151692/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Jun 23, 2015
Decision date	Nov 20, 2015
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioarchitects USA, LLC</b>
Location	New York, NY, US
Contact	Mark E. Ulrich
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151692/> 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 June 3, 2026