

**K152076 PEEK Customized Cranial Implant, PEEK Customized Cranial Implant Priority**Aug 26, 2015  
30 days to decisionK152076 · Product code: **GWO** · Neurology  
Source: <https://www.510kdatabase.net/k152076/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Jul 27, 2015
Decision date	Aug 26, 2015
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker</b>
Location	Portage, MI, US
Contact	Jonathan Schell
Website	<a href="http://www.stryker.com/">http://www.stryker.com/</a>
510(k) history	92 submissions · 92 cleared · 2006-2023

Stryker is a family of eight-wheeled armored fighting vehicles derived from the Canadian LAV III. The vehicles are produced by General Dynamics Land Systems-Canada for the United States Army in London, Ontario. This historical record documents FDA 510(k) cleared devices from total submissions between 2006 and 2023. The company's regulatory portfolio focused primarily on General & Plastic Surgery devices, including advanced imaging systems, LED light sources, and surgical visualization equipment. The company has been inactive, with no clearances recorded in more than five ...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k152076/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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