

**K190229 Stryker PEEK Customized Cranial Implant Kit**Jul 11, 2019  
156 days to decisionK190229 · Product code: **GWO** · Neurology  
Source: <https://www.510kdatabase.net/k190229/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Feb 5, 2019
Decision date	Jul 11, 2019
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker</b>
Location	Portage, MI, US
Contact	Zainab Amini
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 ...