FDA 510(k) Premarket Notification

K153248 PEEK Customized Cranial Implant

CLEARED

Mar 10, 2016
122 days to decision

K153248 · Product code: **GWO** · Neurology
Source: https://www.510kdatabase.net/k153248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Nov 9, 2015
Decision date	Mar 10, 2016
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker**
Location	Portage, MI, US
Contact	Jonathan Schell
Website	http://www.stryker.com/
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 ...