

**K132519 STRYKER CUSTOMIZED MANDIBLE RECON PLATE  
KIT**Dec 6, 2013  
116 days to decisionK132519 · Product code: JEY · Dental  
Source: <https://www.510kdatabase.net/k132519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Aug 12, 2013
Decision date	Dec 6, 2013
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker</b>
Location	Portage, MI, US
Contact	ROB YAMASHITA
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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Device record: <https://www.510kdatabase.net/k132519/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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