

K172921 Stryker Self-Punching ICONIXNov 20, 2017
56 days to decisionK172921 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k172921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 25, 2017
Decision date	Nov 20, 2017
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker
Location	Portage, MI, US
Contact	Katie Farraro
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 ...