

K202355 Stryker Omega PEEK Knotless Anchor SystemNov 13, 2020
86 days to decisionK202355 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k202355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 19, 2020
Decision date	Nov 13, 2020
Days to decision	86 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 ...