

K191046 L10 LED Light Source with AIM, L11 LED Light Source with AIMMay 10, 2019
21 days to decisionK191046 · Product code: **OWN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k191046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Confocal Optical Imaging (OWN)
Date received	Apr 19, 2019
Decision date	May 10, 2019
Days to decision	21 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker
Location	Portage, MI, US
Contact	Agatha Szeliga
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 ...