

K231854 1788 4K Camera System with Advanced Imaging Modality

Sep 20, 2023
89 days to decision

K231854 · Product code: **OWN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k231854/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Jun 23, 2023
Decision date	Sep 20, 2023
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	L12 LED Light Source with AIM

APPLICANT

Company	Stryker
Location	Portage, MI, US
Contact	April Malmborg
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 ...