

**K212511 1688 4K Camera Control Unit with Advanced Imaging Modality (1688010000), AIM 4K Autoclave Camera Head, C-Mount (1688410105), AIM 4K Autoclave Coupler, C-Mount (1688410110)**Nov 4, 2021  
86 days to decisionK212511 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k212511/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Aug 10, 2021
Decision date	Nov 4, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker</b>
Location	Portage, MI, US
Contact	Marlene Fraga
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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