

**K221611 780 nm L11 LED Light Source with AIM**Jun 29, 2022  
26 days to decisionK221611 · Product code: **OWN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k221611/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Confocal Optical Imaging (OWN)     |
| Date received         | Jun 3, 2022                        |
| Decision date         | Jun 29, 2022                       |
| Days to decision      | 26 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        | Michelle Hughes   |
| 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 ...