

**K242513 FloNavi Endoscopic Fluorescence Imaging System  
(OPTO-CAM214K, OPTO-CHD214KE, OPTOCHD214KH, OPTO-  
LED214K)**Oct 23, 2024  
61 days to decisionK242513 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k242513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Aug 23, 2024
Decision date	Oct 23, 2024
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Guangdong Optomedic Technologies, Inc.</b>
Location	Foshan, CN
Contact	Weijuan Guo
510(k) history	9 submissions · 9 cleared · 2023-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242513/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026