

K230407 FloNavi Open Field Fluorescence Imaging SystemJul 17, 2023
152 days to decisionK230407 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230407/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Confocal Optical Imaging (OWN) |
| Date received | Feb 15, 2023 |
| Decision date | Jul 17, 2023 |
| Days to decision | 152 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Guangdong Optomedic Technologies, Inc. |
| Location | Foshan, CN |
| Contact | Alice Lau |
| 510(k) history | 9 submissions · 9 cleared · 2023-2026 |

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