

K230898 FLUOBEAM® LX RedJul 28, 2023
119 days to decisionK230898 · Product code: **QDG** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k230898/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Parathyroid Autofluorescence Imaging Device (QDG)
Date received	Mar 31, 2023
Decision date	Jul 28, 2023
Days to decision	119 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fluoptics Sas
Location	Grenoble, FR
Contact	Marion Boudet
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Getinge
Contact	Rama Hannineh

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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