

K233564 FLUOBEAM® LX Imaging System (FB-LX)Dec 15, 2023
39 days to decisionK233564 · Product code: **QDG** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Parathyroid Autofluorescence Imaging Device (QDG)
Date received	Nov 6, 2023
Decision date	Dec 15, 2023
Days to decision	39 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FLUOBEAM® LX Red Imaging System (FB-LXR)

APPLICANT

Company	Fluoptics Sas (A Getinge Group Company)
Location	Grenoble, FR
Contact	Marion Boudet
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Getinge Group
Contact	Barb Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233564/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026