FDA 510(k) Premarket Notification

K250455 FLUOBEAM LX Imaging System (FBLX)

CLEARED

Apr 17, 2025
58 days to decision

K250455 · Product code: **QDG** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250455/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Parathyroid Autofluorescence Imaging Device (QDG)
Date received	Feb 18, 2025
Decision date	Apr 17, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FLUOBEAM LM Imaging System (FBLM)

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