

K190891 Fluobeam LXJul 31, 2019
117 days to decisionK190891 · Product code: **QDG** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k190891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Parathyroid Autofluorescence Imaging Device (QDG)
Date received	Apr 5, 2019
Decision date	Jul 31, 2019
Days to decision	117 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fluoptics
Location	Orinda, CA, US
Contact	Odile Allard
510(k) history	3 submissions · 2 cleared · 2014-2019

REGULATORY CONSULTANT

Consulting firm	Daniel & Daniel Consulting, LLC
Contact	Michael A. Daniel

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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