FDA 510(k) Premarket Notification

K190891 Fluobeam LX

CLEARED

Jul 31, 2019
117 days to decision

K190891 · 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