

**K132475 FLUOBEM 800 CLINIC LASER IMAGING DEVICE AND
FLUCASE 800 CONTROL SYSTEM**May 7, 2014
273 days to decisionK132475 · Product code: **OWN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k132475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Aug 7, 2013
Decision date	May 7, 2014
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132475/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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