

K163185 OptiLux LED IlluminatorNov 21, 2016
7 days to decisionK163185 · Product code: **HBI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Illuminator, Fiberoptic, Surgical Field (HBI)
Date received	Nov 14, 2016
Decision date	Nov 21, 2016
Days to decision	7 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	Isolux, LLC
Location	Naples, FL, US
Contact	NIKOLAOS ANDREOULAKIS
510(k) history	3 submissions · 3 cleared · 2005-2016

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