

K110528 INTEGRA LED SURGICAL HEADLIGHT SYSTEMMay 11, 2011
76 days to decisionK110528 · Product code: **FSR** · Ophthalmic
Source: <https://www.510kdatabase.net/k110528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Headband, Surgical (FSR)
Date received	Feb 24, 2011
Decision date	May 11, 2011
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Integra LifeSciences Corporation
Location	Planisboro, NJ, US
Contact	STEPHANIE SHEESLEY
510(k) history	65 submissions · 65 cleared · 2004-2025

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