

K093465 FUSION SYSTEMJan 5, 2010
60 days to decisionK093465 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k093465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Nov 6, 2009
Decision date	Jan 5, 2010
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eclipsemed Global, Inc.
Location	Dallas, TX, US
Contact	IGOR GRADOV
510(k) history	2 submissions · 2 cleared · 2010-2010

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