

K140460 MACH LED 2SCApr 3, 2014
38 days to decisionK140460 · Product code: **FSY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k140460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Light, Surgical, Ceiling Mounted (FSY)
Date received	Feb 24, 2014
Decision date	Apr 3, 2014
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dr. Mach GmbH & Co. KG
Location	Ebersberg, DE
Contact	GUDRUN BUSCH, PH.D.
510(k) history	4 submissions · 4 cleared · 2010-2014

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