

K093009 MACH LED SCApr 1, 2010
184 days to decisionK093009 · Product code: **FSY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k093009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Surgical, Ceiling Mounted (FSY)
Date received	Sep 29, 2009
Decision date	Apr 1, 2010
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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