

**K140461 MACH LED 2MC**Apr 3, 2014  
38 days to decisionK140461 · Product code: **FSY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k140461/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140461/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 7, 2026