

**K090378 CHROMOPHARE E 668**Feb 23, 2009  
6 days to decisionK090378 · Product code: **FSY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k090378/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Surgical, Ceiling Mounted (FSY)
Date received	Feb 17, 2009
Decision date	Feb 23, 2009
Days to decision	6 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Berchtold GmbH &amp; Co. KG</b>
Location	Charleston, SC, US
Contact	HEATH HINES
510(k) history	2 submissions · 2 cleared · 2009-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090378/> 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 15, 2026