

K080857 CHROMOPHARE E-SERIESApr 10, 2008
14 days to decisionK080857 · Product code: **FSY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k080857/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Surgical, Ceiling Mounted (FSY)
Date received	Mar 27, 2008
Decision date	Apr 10, 2008
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Berchtold Holding GmbH
Location	Tuttlingen, DE
Contact	SILKE GORAL
510(k) history	16 submissions · 16 cleared · 1992-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080857/> Data sourced from FDA 510(k) public records (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. - Generated June 24, 2026