

**K061690 SURGICAL HEADLIGHT**Sep 15, 2006  
92 days to decisionK061690 · Product code: **FST** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k061690/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Surgical, Fiberoptic (FST)
Date received	Jun 15, 2006
Decision date	Sep 15, 2006
Days to decision	92 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gulf Medical Fiberoptics</b>
Location	Oldsmar, FL, US
Contact	MARCELINO AFANADOR
510(k) history	2 submissions · 2 cleared · 2002-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061690/> 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 29, 2026