

**K122593 PRECISION ENDOSCOPIC INFRARED COAGULATOR**Sep 13, 2012  
20 days to decisionK122593 · Product code: **FEH** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k122593/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Flexible Suction Coagulator (FEH)
Date received	Aug 24, 2012
Decision date	Sep 13, 2012
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary
Other names	MODEL 5100 SINGLE-USE DISPOSABLE MAXI-GUIDE FLEXIBLE LIGHTGUIDE; MODEL 5100-2

**APPLICANT**

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Company	<b>Optim, LLC</b>
Location	Sturbridge, MA, US
Contact	JEFF BARRETT
510(k) history	3 submissions · 3 cleared · 2012-2021

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122593/> 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 May 27, 2026