

**K083275 PRECISION ENDOSCOPIC INFRARED COAGULATOR**Jun 9, 2009  
215 days to decisionK083275 · Product code: **KNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k083275/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Nov 6, 2008
Decision date	Jun 9, 2009
Days to decision	215 days
Third-party review	No
Summary / Statement	Statement
Other names	MODEL 5100 SINGLE- USE DISPOSABLE MAXI-GUIDE FLEXIBLE LIGHTGUIDE; MODEL 5100-2

**APPLICANT**

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Company	<b>Max Endoscopy, Inc.</b>
Location	Macedonia, OH, US
Contact	MICHAEL WOLF
510(k) history	2 submissions · 2 cleared · 2008-2009

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083275/> 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 22, 2026