

**K003953 INDIGO DIFFUSER-TIP FIBEROPTIC WITH  
TEMPERATURE SENSING OPTION, MODEL LF001**Mar 16, 2001  
85 days to decisionK003953 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k003953/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 21, 2000
Decision date	Mar 16, 2001
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ethicon Endo-Surgery, Inc.</b>
Location	Cincinnati, OH, US
Contact	JACKIE HUGHES
Website	<a href="http://www.ethiconendo.com/">http://www.ethiconendo.com/</a>
510(k) history	112 submissions · 112 cleared · 1992-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003953/> 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 5, 2026