

**K944704 OPTILITE (TM) VII FIBEROPTIC ACCESSORIES  
ROTALASE (TM) ANGLE DELIVERY SYSTEMSN AND  
ACCESSORIES**Jan 6, 1995  
105 days to decisionK944704 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k944704/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 23, 1994
Decision date	Jan 6, 1995
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Xintec Corporation</b>
Location	Oakland, CA, US
Contact	MARILYN M CHOU
510(k) history	26 submissions · 26 cleared · 1990-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944704/>; 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 21, 2026