

**K073158 SCULPTURE 2.94 ER:YAG SYSTEM**Aug 27, 2008  
293 days to decisionK073158 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k073158/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 8, 2007
Decision date	Aug 27, 2008
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hoya Conbio, Inc.</b>
Location	Fremont, CA, US
Contact	LIZA BURNS
510(k) history	7 submissions · 7 cleared · 2006-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073158/> 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 23, 2026