

**K032805 MODIFICATION TO VASCULAR SOLUTIONS VARI-LASE ENDOVENOUS LASER PROCEDURE KIT**Oct 1, 2003  
22 days to decisionK032805 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k032805/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 9, 2003
Decision date	Oct 1, 2003
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vascular Solutions, Inc.</b>
Location	Minneapolis, MN, US
Contact	DEBORAH JENSEN
Website	<a href="http://vasc.com/">http://vasc.com/</a>
510(k) history	103 submissions · 102 cleared · 2002-2018

Vascular Solutions, Inc. specialized in cardiovascular interventional devices with a manufacturing facility in Minneapolis, US. The company developed a broad portfolio of catheters, guidewires, and vascular access systems for interventional cardiology and radiology procedures. The company received FDA 510(k) clearances from total submissions between 2002 and 2018. All submissions in the regulatory record were cleared. Cardiovascular devices dominated the company's portfolio, including mechanical thrombectomy systems, aspiration systems, guidewires, and vascular closure te...

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