

K062822 VARI-LASE ENDOVENOUS LASER CONSOLE, MODEL 7500Nov 21, 2006
62 days to decisionK062822 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k062822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 20, 2006
Decision date	Nov 21, 2006
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Solutions, Inc.
Location	Minneapolis, MN, US
Contact	PATRICE STROMBERG
Website	http://vasc.com/
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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Device record: <https://www.510kdatabase.net/k062822/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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