

**K113140 VARI-LASE WREFIBER LASER FIBER**Dec 22, 2011  
58 days to decisionK113140 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k113140/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Special                                 |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Oct 25, 2011                            |
| Decision date         | Dec 22, 2011                            |
| Days to decision      | 58 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Vascular Solutions, Inc.</b>                 |
| Location       | Minneapolis, MN, US                             |
| Contact        | JENIFER RUETHER                                 |
| 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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