FDA 510(k) Premarket Notification

K072332 VARI-LASE WIRE FIBER

CLEARED

Jan 10, 2008
143 days to decision

K072332 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k072332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 20, 2007
Decision date	Jan 10, 2008
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vascular Solutions, Inc.**
Location	Minneapolis, MN, US
Contact	DEBORAH NEYMARK
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...