FDA 510(k) Premarket Notification

CLEARED

K032204 MODIFICATION TO VASCULAR SOLUTIONS VARI-LASE ENDOVENOUS LASER PROCEDURE KIT

Aug 20, 2003
33 days to decision

K032204 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k032204/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 18, 2003
Decision date	Aug 20, 2003
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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