

K041930 VARILITE LASER SYSTEMSep 10, 2004
53 days to decisionK041930 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k041930/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 19, 2004
Decision date	Sep 10, 2004
Days to decision	53 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Iridex Corporation
Location	Mountain View, CA, US
Contact	JOHN JOSSY
Website	http://www.iridex.com/
510(k) history	9 submissions · 9 cleared · 2004-2023

Iridex Corporation is a worldwide leader in developing, manufacturing, and marketing innovative laser-based medical systems for the ophthalmology market. Founded in 1989, the company specializes in ophthalmic laser devices, delivery systems, and surgical instrumentation. Iridex maintains a manufacturing facility in Mountain View, California and serves customers globally through direct sales and approximately 60 independent distributors across over 100 countries. The company has received FDA 510(k) clearances from total submissions between 2004 and 2023. Iridex's regulator...
