

K162416 IRIDEX Cyclo G6 Laser System, G-Probe IlluminateSep 29, 2016
30 days to decisionK162416 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 30, 2016
Decision date	Sep 29, 2016
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Iridex Corporation
Location	Mountain View, CA, US
Contact	KATHY MAYNOR
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...
