

K143154 IRIDEX CycloG6 Laser System, MicroPulse P3 Drive, G-Probe(RFID)Jan 2, 2015
60 days to decisionK143154 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k143154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 3, 2014
Decision date	Jan 2, 2015
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Iridex Corporation
Location	Mountain View, CA, US
Contact	PAUL H HARDIMAN
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...

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Device record: <https://www.510kdatabase.net/k143154/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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