

**K230228 Iridex 532 Laser**Feb 23, 2023  
27 days to decisionK230228 · Product code: **HQF** · Ophthalmic  
Source: <https://www.510kdatabase.net/k230228/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laser, Ophthalmic (HQF)
Date received	Jan 27, 2023
Decision date	Feb 23, 2023
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary
Other names	Iridex 577 Laser; Iridex Laser (532 nm and 577 nm models)

**APPLICANT**

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Company	<b>Iridex Corporation</b>
Location	Mountain View, CA, US
Contact	Mari Iwamoto
Website	<a href="http://www.iridex.com/">http://www.iridex.com/</a>
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...