FDA 510(k) Premarket Notification

K213592 Iridex 810 Laser

CLEARED

Mar 23, 2022
131 days to decision

K213592 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k213592/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laser, Ophthalmic (HQF)
Date received	Nov 12, 2021
Decision date	Mar 23, 2022
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Iridex Corporation**
Location	Mountain View, CA, US
Contact	Bill Hyatt
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...