FDA 510(k) Premarket Notification

K181662 Iridex TruFocus LIO Premiere

CLEARED

Sep 5, 2018
72 days to decision

K181662 · Product code: **GEX** · Ophthalmic
Source: https://www.510kdatabase.net/k181662/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 25, 2018
Decision date	Sep 5, 2018
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Iridex Corporation**
Location	Mountain View, CA, US
Contact	Edward J. Sinclair
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...