FDA 510(k) Premarket Notification

CLEARED

K212630 Tango, Tango Reflex, Ultra Q, Ultra Q Reflex, Solo

Dec 16, 2021
119 days to decision

K212630 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k212630/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Aug 19, 2021
Decision date	Dec 16, 2021
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ellex Medical Pty, Ltd.**
Location	Adelaide, South Australia, AU
Contact	Rashmi Pillay
510(k) history	13 submissions · 13 cleared · 1997-2022

REGULATORY CONSULTANT

Consulting firm	**O'Connell Regulatory Consultants, Inc.**
Contact	Maureen O'Connell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov