

K222395 Tango Neo, Tango Reflex Neo, Ultra Q Reflex NeoNov 2, 2022
86 days to decisionK222395 · Product code: **HQF** · Ophthalmic
Source: <https://www.510kdatabase.net/k222395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Aug 8, 2022
Decision date	Nov 2, 2022
Days to decision	86 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](https://accessdata.fda.gov)

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