

**K240512 Tixel i (TXLI0001)**Nov 4, 2024  
256 days to decisionK240512 · Product code: **ORZ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k240512/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eyelid Thermal Pulsation System (ORZ)
Date received	Feb 22, 2024
Decision date	Nov 4, 2024
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novoxel , Ltd.</b>
Location	Netanya, IL
Contact	Daniela Dov Elmaz
510(k) history	3 submissions · 3 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Pathways Group, Inc.</b>
Contact	Anne-Marie Ripley

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

**CLINICAL EVIDENCE - NCT05162261****to Evaluate the Effectiveness and Safety of the Tixel® , VS LipiFlow® in the Treatment of Meibomian Gland Dysfunction**

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Status	Completed
Enrollment	109 patients (actual)
Study sites	5 sites
Condition studied	Meibomian Gland Dysfunction; Dry Eye Syndromes; Dry Eye
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Sep 28, 2023
Sponsor	Novoxel Ltd. (Industry)

**Primary outcome**

Changes in Tear Break Up Times (TBUT) to the 4-weeks Follow-up Exam

**Secondary outcome**

Changes in Patient OSDI

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05162261](https://clinicaltrials.gov/study/NCT05162261)