

K200400 Systane iLux2May 21, 2020
93 days to decisionK200400 · Product code: **ORZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k200400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eyelid Thermal Pulsation System (ORZ)
Date received	Feb 18, 2020
Decision date	May 21, 2020
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tear Film Innovations, Inc.
Location	San Diego, CA, US
Contact	Neal Hartman
510(k) history	2 submissions · 2 cleared · 2017-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200400/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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