

K192623 LipiFlow Thermal Pulsation SystemOct 22, 2019
29 days to decisionK192623 · Product code: **ORZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k192623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Eyelid Thermal Pulsation System (ORZ)
Date received	Sep 23, 2019
Decision date	Oct 22, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tearscience, Inc.
Location	Morrisville, NC, US
Contact	Michelle Ricafort
510(k) history	9 submissions · 8 cleared · 2009-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192623/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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