

K252455 FSYX Ocular Pressure Adjusting PumpApr 30, 2026
268 days to decisionK252455 · Product code: **QQJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k252455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Applicator, Negative Pressure, External, Ocular (QQJ)
Date received	Aug 5, 2025
Decision date	Apr 30, 2026
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Balance Ophthalmics, Inc.
Location	Sioux Falls, SD, US
Contact	Gary Mocnik
Website	https://balanceophthalmics.com
510(k) history	2 submissions · 1 cleared · 2024-2026

Balance Ophthalmics, Inc. is dedicated to innovative ophthalmic solutions for glaucoma treatment. The company, based in Sioux Falls, South Dakota, focuses on non-pharmaceutical and non-surgical therapies to lower intraocular pressure. Their team brings over 100 years of specialized expertise in eye care research and development. The company has received FDA 510(k) clearance from total submissions. Balance Ophthalmics specializes in ophthalmic devices, representing 100% of its regulatory submissions. The company achieved its first clearance in 2024 and remains active, with...