

K221263 Aqua Naina Plus Sterile Saline SolutionOct 12, 2022
163 days to decisionK221263 · Product code: **LPN** · Ophthalmic
Source: <https://www.510kdatabase.net/k221263/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accessories, Soft Lens Products (LPN)
Date received	May 2, 2022
Decision date	Oct 12, 2022
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chemtex USA, Inc.
Location	Fairfield, NJ, US
Contact	Haribabu Talasila
510(k) history	2 submissions · 2 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Eyereg Consulting, Inc.
Contact	Bret Andre

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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