

**K193441 Aqua Naina Sterile Saline Solution**May 26, 2020  
167 days to decisionK193441 · Product code: **LPN** · Ophthalmic  
Source: <https://www.510kdatabase.net/k193441/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Soft Lens Products (LPN)
Date received	Dec 11, 2019
Decision date	May 26, 2020
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193441/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026