

K242956 LDS NeedleOct 25, 2024
30 days to decisionK242956 · Product code: **QNS** · General Hospital
Source: <https://www.510kdatabase.net/k242956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Low Dead Space Needle, Single Lumen, Hypodermic (QNS)
Date received	Sep 25, 2024
Decision date	Oct 25, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	OcuSafe® LDS Needle; SteriCap® LDS Safety Needle; VitreJect® LDS Safety Needle

APPLICANT

Company	Ocuject, LLC
Location	Newport Beach, CA, US
Contact	Leonid Lerner
510(k) history	8 submissions · 8 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Resources Group, Inc.
Contact	Julie Stephens

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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