FDA 510(k) Premarket Notification

K230959 VitreJect® Needle

CLEARED

Sep 14, 2023
163 days to decision

K230959 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k230959/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 4, 2023
Decision date	Sep 14, 2023
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	OcuSafe® 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	**Namsa**
Contact	Heidi Busz

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