FDA 510(k) Premarket Notification

# K233343 SteriCap Safety Needle

**CLEARED**

Nov 27, 2023
59 days to decision

K233343 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k233343/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Sep 29, 2023 |
| Decision date | Nov 27, 2023 |
| Days to decision | 59 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | VitreJect Safety Needle |

## APPLICANT

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