FDA 510(k) Premarket Notification

**CLEARED**

# K211210 Sterile Auto-Disable Syringes with/without Needle for Single Use

Jan 27, 2022
279 days to decision

K211210 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k211210/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Syringe, Piston (FMF) |
| Date received | Apr 23, 2021 |
| Decision date | Jan 27, 2022 |
| Days to decision | 279 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Azur Medical Company, Inc.** |
| Location | Richmond, VA, US |
| Contact | Di Zhao |
| 510(k) history | 4 submissions · 4 cleared · 2021-2024 |