FDA 510(k) Premarket Notification

# K190538 NIO-I

**CLEARED**

Oct 7, 2019
217 days to decision

K190538 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k190538/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Mar 4, 2019 |
| Decision date | Oct 7, 2019 |
| Days to decision | 217 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Waismed, Ltd.** |
| Location | Ra'Ananna, IL |
| Contact | Maya Shuvi |
| 510(k) history | 7 submissions · 7 cleared · 1998-2021 |