

K190538 NIO-IOct 7, 2019
217 days to decisionK190538 · 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

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190538/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026