

**K211968 NIO+ Adult**Jul 22, 2021  
28 days to decisionK211968 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k211968/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 24, 2021
Decision date	Jul 22, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Waismed, Ltd.</b>
Location	Ra&apos;Ananna, IL
Contact	Shifra Hoch
510(k) history	7 submissions · 7 cleared · 1998-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211968/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026