

K160805 NIO-PJun 23, 2016
92 days to decisionK160805 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k160805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 23, 2016
Decision date	Jun 23, 2016
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Waismed, Ltd.
Location	Ra'ananna, IL
Contact	Einat Swisa
510(k) history	7 submissions · 7 cleared · 1998-2021

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