FDA 510(k) Premarket Notification

K160805 NIO-P

CLEARED

Jun 23, 2016
92 days to decision

K160805 · 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