FDA 510(k) Premarket Notification

K211968 NIO+ Adult

CLEARED

Jul 22, 2021
28 days to decision

K211968 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k211968/

SUBMISSION DETAILS

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

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