FDA 510(k) Premarket Notification

K231519 Revital Cady

CLEARED

Nov 6, 2023
165 days to decision

K231519 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k231519/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	May 25, 2023
Decision date	Nov 6, 2023
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Revital Healthcare (Epz) Limited**
Location	Mombasa, KE
Contact	Ankur Vora
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Alceon Medtech Consulting**
Contact	Atonu Dutta

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov