FDA 510(k) Premarket Notification

CLEARED

K221702 CompuFlo Epidural Computer Controlled Anesthesia System

Feb 25, 2023
257 days to decision

K221702 · Product code: **FMF** · Anesthesiology
Source: https://www.510kdatabase.net/k221702/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jun 13, 2022
Decision date	Feb 25, 2023
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Milestone Scientific, Inc.**
Location	Washington, Dc, DC, US
Contact	Arjan Haverhals
510(k) history	4 submissions · 4 cleared · 2006-2023

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Kevin Go

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