

K230718 UTC 3mL Medication CartridgeJun 15, 2023
92 days to decisionK230718 · Product code: **MRZ** · General Hospital
Source: <https://www.510kdatabase.net/k230718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Pump, Infusion (MRZ)
Date received	Mar 15, 2023
Decision date	Jun 15, 2023
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gilero, LLC
Location	Morrisville, NC, US
Contact	Jessica Czamanski
510(k) history	2 submissions · 2 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230718/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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