FDA 510(k) Premarket Notification

CLEARED

K223656 AmeriWater MediQA Reverse Osmosis System (MSP3HF)

Feb 13, 2023
69 days to decision

K223656 · Product code: **FIP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k223656/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Subsystem, Water Purification (FIP)
Date received	Dec 6, 2022
Decision date	Feb 13, 2023
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**AmeriWater, LLC**
Location	Dayton, OH, US
Contact	Brian Bowman
510(k) history	1 submissions · 1 cleared · 2023-2023