

K213507 AquaAJul 27, 2022
268 days to decisionK213507 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k213507/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Nov 1, 2021
Decision date	Jul 27, 2022
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care Rental Therapies Group, LLC
Location	Waltham, MA, US
Contact	Denise Oppermann
510(k) history	1 submissions · 1 cleared · 2022-2022

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