

K211035 U9000 Plus UltrafilterOct 19, 2021
195 days to decisionK211035 · Product code: **FIP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Apr 7, 2021
Decision date	Oct 19, 2021
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Healthcare Corporation
Location	Round Lake, IL, US
Contact	Carina Pforr
510(k) history	61 submissions · 60 cleared · 2004-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211035/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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