

**K991519 AMERIWATER PURIFICATION SYSTEM FOR HEMODIALYSIS**

Apr 14, 2000  
350 days to decision

K991519 · Product code: **FIP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k991519/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Apr 30, 1999
Decision date	Apr 14, 2000
Days to decision	350 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ameriwater</b>
Location	Dayton, OH, US
Contact	SANDRA E MONSMAN
510(k) history	11 submissions · 11 cleared · 2000-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k991519/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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