

K092481 HEMODIALYSIS CARBON EXCHANGE, DUAL BED DEIONIZER EXCHANGE, MIXED BED DEIONIZER EXCHANGE, MODEL .60MAW,1.2MAW,3.6MAW, 1.2

Apr 2, 2010
232 days to decision

K092481 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k092481/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Aug 13, 2009
Decision date	Apr 2, 2010
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	New Aqua, LLC (Db a Aqua Systems)
Location	Avon, IN, US
Contact	NEVIN RUDIE
510(k) history	1 submissions · 1 cleared · 2010-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k092481/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 21, 2026