

**K041163 ISOPURE COMPLETE WATER SYSTEM FOR
HEMODIALYSIS, MD 400 AND MD 600 SERIES**Oct 7, 2004
157 days to decisionK041163 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k041163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	May 3, 2004
Decision date	Oct 7, 2004
Days to decision	157 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Isopure, Corp.
Location	Simpsonville, KY, US
Contact	KEVIN GILLESPIE
510(k) history	5 submissions · 5 cleared · 2000-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041163/> 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 28, 2026