

**K974899 GAMBRO CENTRAL WATER TREATMENT SYSTEM
CWP 100 - WRO H**

Sep 23, 1998
267 days to decision

K974899 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k974899/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Dec 30, 1997
Decision date	Sep 23, 1998
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Healthcare
Location	Oklahoma City, OK, US
Contact	JEFFREY R SHIDEMAN
510(k) history	13 submissions · 13 cleared · 1996-2000

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k974899/> 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 29, 2026