

K003957 DIACLEAR ULTRAFILTERNov 1, 2001
315 days to decisionK003957 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k003957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Dec 21, 2000
Decision date	Nov 1, 2001
Days to decision	315 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gambro Renal Products
Location	Lakewood, CO, US
Contact	SUZANNE DENNIS
510(k) history	24 submissions · 23 cleared · 2000-2012

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