

K011148 ULTRACONCENTRATOR SYSTEMJun 13, 2001
58 days to decisionK011148 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Apr 16, 2001
Decision date	Jun 13, 2001
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Interpore Cross Intl.
Location	Irvine, CA, US
Contact	PROSIE REY-FESSLER
510(k) history	39 submissions · 38 cleared · 1998-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011148/> 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 May 20, 2026