FDA 510(k) Premarket Notification

K883748 RENAK-E & RENEK-A SERIES HOLLOW FIBER DIALYZERS

CLEARED

Jan 31, 1989
152 days to decision

K883748 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k883748/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Sep 1, 1988
Decision date	Jan 31, 1989
Days to decision	152 days
Third-party review	No

APPLICANT

Company	**Kawasumi Laboratories Co., Ltd.**
Location	Canoga Park, CA, US
Contact	KENJIRO TANI
510(k) history	18 submissions · 18 cleared · 1987-2000