FDA 510(k) Premarket Notification

K933619 PD-PAK

CLEARED

Feb 22, 1994
218 days to decision

K933619 · Product code: **MLW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k933619/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Peritoneal Dialysate (MLW)
Date received	Jul 19, 1993
Decision date	Feb 22, 1994
Days to decision	218 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**General Medical Mfg. Co.**
Location	Richmond, VA, US
Contact	ALFRED H GREBE
510(k) history	1 submissions · 1 cleared · 1994-1994