FDA 510(k) Premarket Notification

K970700 FRESENIUS POLYSULFONE HEMODIALYZERS, BOTH LOW AND HIGH FLUX

CLEARED

Sep 15, 1998
567 days to decision

K970700 · Product code: **MSE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k970700/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialyzer, Re-use, Low Flux (MSE)
Date received	Feb 25, 1997
Decision date	Sep 15, 1998
Days to decision	567 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Fresenius USA, Inc.**
Location	Walker, MI, US
Contact	TOM FOLDEN
510(k) history	38 submissions · 37 cleared · 1984-1999