FDA 510(k) Premarket Notification

K971053 ROCKWELL MEDICAL SUPPLY,LLC. BICARBONATE SOLUTION CONCENTRATES FOR BICARBONATE DIALYSIS

CLEARED

Jun 16, 1997
84 days to decision

K971053 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k971053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Mar 24, 1997
Decision date	Jun 16, 1997
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**International Medical Products, Inc.**
Location	Minneapolis, MN, US
Contact	JEFFREY R SHIDEMAN
510(k) history	9 submissions · 9 cleared · 1986-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k971053/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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