FDA 510(k) Premarket Notification

K913223 STERILE DISPOSABLE URINE COLLECTOR & ACCESSORIES

CLEARED

Sep 4, 1991
47 days to decision

K913223 · Product code: **KNX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k913223/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Urine, (and Accessories) For Indwelling Catheter (KNX)
Date received	Jul 19, 1991
Decision date	Sep 4, 1991
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medical Device Inspection Co., Inc.**
Location	Great Neck, NY, US
Contact	ALAN P SCHWARTZ
510(k) history	30 submissions · 26 cleared · 1990-1995