FDA 510(k) Premarket Notification

K902417 BAG, URINE

CLEARED

Jul 16, 1990
46 days to decision

K902417 · Product code: **KNX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k902417/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Urine, (and Accessories) For Indwelling Catheter (KNX)
Date received	May 31, 1990
Decision date	Jul 16, 1990
Days to decision	46 days
Third-party review	No

APPLICANT

Company	**Gainor Medical Europe, Ltd.**
Location	Mcdonough, GA, US
Contact	MARK GAINOR
510(k) history	13 submissions · 13 cleared · 1990-1994