FDA 510(k) Premarket Notification

K821978 STERILE URETHRAL CATHETERIZATION SET

CLEARED

Aug 25, 1982
50 days to decision

K821978 · Product code: **KNX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k821978/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Urine, (and Accessories) For Indwelling Catheter (KNX)
Date received	Jul 6, 1982
Decision date	Aug 25, 1982
Days to decision	50 days
Third-party review	No

APPLICANT

Company	**Medical Devices, Inc.**
Location	Mchenry, IL, US
510(k) history	49 submissions · 47 cleared · 1977-2001