FDA 510(k) Premarket Notification

K801629 COVER-ALL MALE INCONTINENCE DEVICE

CLEARED

Aug 12, 1980
28 days to decision

K801629 · Product code: **KNX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k801629/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Urine, (and Accessories) For Indwelling Catheter (KNX)
Date received	Jul 15, 1980
Decision date	Aug 12, 1980
Days to decision	28 days
Third-party review	No

APPLICANT

Company	**The Urology Group**
Location	Mchenry, IL, US
510(k) history	6 submissions · 6 cleared · 1980-1984