FDA 510(k) Premarket Notification

K821161 EXTERNAL URINARY MALE INCONTINENCE DEV

CLEARED

May 10, 1982
14 days to decision

K821161 · Product code: **KNX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k821161/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Urine, (and Accessories) For Indwelling Catheter (KNX)
Date received	Apr 26, 1982
Decision date	May 10, 1982
Days to decision	14 days
Third-party review	No

APPLICANT

Company	**The Healthcare Group Laboratories, Inc.**
Location	Mchenry, IL, US
510(k) history	29 submissions · 29 cleared · 1980-1985