FDA 510(k) Premarket Notification

K885323 DACOMED EXTERNAL MALE CONTINENCE DEVICE

CLEARED

Feb 8, 1989
42 days to decision

K885323 · Product code: **FHA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k885323/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Penile (FHA)
Date received	Dec 28, 1988
Decision date	Feb 8, 1989
Days to decision	42 days
Third-party review	No

APPLICANT

Company	**Dacomed Corp.**
Location	Mchenry, IL, US
Contact	MARY M WILEN
510(k) history	20 submissions · 20 cleared · 1981-1995