FDA 510(k) Premarket Notification

K803111 ERECTAID

CLEARED

Jan 23, 1981
44 days to decision

K803111 · Product code: **FAE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k803111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Dec 10, 1980
Decision date	Jan 23, 1981
Days to decision	44 days
Third-party review	No

APPLICANT

Company	**Burditt & Calkins-Siemens-Elema**
Location	Mchenry, IL, US
Contact	FRANK GEROW
510(k) history	10 submissions · 10 cleared · 1976-1984