FDA 510(k) Premarket Notification

K800611 BOUGIE A BOULE

CLEARED

Apr 8, 1980
22 days to decision

K800611 · Product code: **KOE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k800611/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Urethral (KOE)
Date received	Mar 17, 1980
Decision date	Apr 8, 1980
Days to decision	22 days
Third-party review	No

APPLICANT

Company	**G.D. Searle and Co.**
Location	Mchenry, IL, US
510(k) history	56 submissions · 56 cleared · 1976-1982

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k800611/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026