FDA 510(k) Premarket Notification

K780484 SILASTIC BRAND PENILE IMPLANT

CLEARED

Jul 17, 1978
112 days to decision

K780484 · Product code: **FIQ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k780484/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, A-v Shunt (FIQ)
Date received	Mar 27, 1978
Decision date	Jul 17, 1978
Days to decision	112 days
Third-party review	No

APPLICANT

Company	**Dow Corning Corp. Healthcare Industries Materials**
Location	Mchenry, IL, US
510(k) history	31 submissions · 31 cleared · 1976-1985