FDA 510(k) Premarket Notification

K820237 COBE ACUFLEX FSN, #15-208

CLEARED

Mar 10, 1982
41 days to decision

K820237 · Product code: **LFK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k820237/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Femoral (LFK)
Date received	Jan 28, 1982
Decision date	Mar 10, 1982
Days to decision	41 days
Third-party review	No

APPLICANT

Company	**Cobe Laboratories, Inc.**
Location	Mchenry, IL, US
Website	https://www.gambro.com
510(k) history	77 submissions · 77 cleared · 1976-1993