FDA 510(k) Premarket Notification

K791182 ACMI RIGI-FLEX NEPHORSCOPE

CLEARED

Jul 30, 1979
35 days to decision

K791182 · Product code: **FGA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k791182/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Nephroscope (FGA)
Date received	Jun 25, 1979
Decision date	Jul 30, 1979
Days to decision	35 days
Third-party review	No

APPLICANT

Company	**American Cystocope Makers, Inc.**
Location	Mchenry, IL, US
510(k) history	9 submissions · 9 cleared · 1976-1983