FDA 510(k) Premarket Notification

K770833 FLUORETEC-M

CLEARED

Jun 8, 1977
33 days to decision

K770833 · Product code: **GMY** · Microbiology
Source: https://www.510kdatabase.net/k770833/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Fluorescent, All Types, Escherichia Coli (GMY)
Date received	May 6, 1977
Decision date	Jun 8, 1977
Days to decision	33 days
Third-party review	No

APPLICANT

Company	**Pfizer, Inc.**
Location	Mchenry, IL, US
510(k) history	30 submissions · 30 cleared · 1977-2018

Pfizer, Inc. is an American multinational pharmaceutical and biotechnology corporation headquartered in Manhattan, New York City. Founded in 1849, Pfizer is one of the oldest pharmaceutical companies in North America. Pfizer's FDA 510(k) regulatory record includes cleared devices from total submissions, spanning 1977 to 2018. The company's device portfolio demonstrates strength in orthopedic devices, including surgical implants and fixation systems. This regulatory activity is now historical, with no clearances recorded in the past five years. The company's cleared device...