FDA 510(k) Premarket Notification

K780413 LOW IIONIC STRENGTH SOLUTION

CLEARED

Apr 24, 1978
40 days to decision

K780413 · Product code: **KSG** · Hematology
Source: https://www.510kdatabase.net/k780413/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Potentiating For In Vitro Diagnostic Use (KSG)
Date received	Mar 15, 1978
Decision date	Apr 24, 1978
Days to decision	40 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...