

K782086 AM-PEN SCREENFeb 1, 1979
49 days to decisionK782086 · Product code: **JTO** · Microbiology
Source: <https://www.510kdatabase.net/k782086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Discs, Strips And Reagents, Microorganism Differentiation (JTO)
Date received	Dec 14, 1978
Decision date	Feb 1, 1979
Days to decision	49 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...

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Device record: <https://www.510kdatabase.net/k782086/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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