FDA 510(k) Premarket Notification

K850886 COMPRESSION HIP SCREW SYSTEM

CLEARED

Apr 19, 1985
46 days to decision

K850886 · Product code: **KIT** · Pathology
Source: https://www.510kdatabase.net/k850886/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media And Components, Synthetic Cell And Tissue Culture (KIT)
Date received	Mar 4, 1985
Decision date	Apr 19, 1985
Days to decision	46 days
Third-party review	No

APPLICANT

Company	**Pfizer, Inc.**
Location	Mchenry, IL, US
Contact	RONALD DUCHENE
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...