FDA 510(k) Premarket Notification

K850441 MEC INTRAMEDULLARY ROD

CLEARED

Apr 19, 1985
73 days to decision

K850441 · Product code: **HSB** · Orthopedic
Source: https://www.510kdatabase.net/k850441/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 5, 1985
Decision date	Apr 19, 1985
Days to decision	73 days
Third-party review	No

APPLICANT

Company	**Pfizer, Inc.**
Location	Mchenry, IL, US
Contact	BARBARA G RAMSEYER
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...