

K850403 MEC DISTAL FEMORAL BOLTJul 15, 1985
164 days to decisionK850403 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k850403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Feb 1, 1985
Decision date	Jul 15, 1985
Days to decision	164 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...