

K070561 KMEDIC INTERNAL/EXTERNAL FIXATION DEVICESMay 25, 2007
87 days to decisionK070561 · Product code: **HTY** · Orthopedic
Source: <https://www.510kdatabase.net/k070561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Feb 27, 2007
Decision date	May 25, 2007
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflex Medical
Location	Fall River, MA, US
Contact	LORI HAYS
510(k) history	39 submissions · 39 cleared · 2003-2025

Teleflex Medical is an American medical device company headquartered in Wayne, Pennsylvania, with operations in Fall River, US. The company is a major provider of specialty medical devices for critical care and surgical procedures. Teleflex Medical has received FDA 510(k) clearances from total submissions since 2003. The company maintains active regulatory engagement, with the latest clearance in 2025. Its cleared devices span multiple specialties including anesthesiology, general and plastic surgery, cardiovascular, and vascular access systems. The company's product port...

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