

**K180588 FAST1™ Intraosseous Infusion System**Apr 17, 2018  
42 days to decisionK180588 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k180588/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 6, 2018
Decision date	Apr 17, 2018
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary
Other names	FASTResponder™ Sternal Intraosseous Device

**APPLICANT**

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Company	<b>Teleflex Medical</b>
Location	Fall River, MA, US
Contact	Ying Zhao
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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