

**K043258 MODIFIED TFX MEDICAL SAFETY NEEDLE WITH INTRODUCER, PART NO. T4634-02**Dec 16, 2004  
22 days to decisionK043258 · Product code: **KNT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k043258/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Nov 24, 2004
Decision date	Dec 16, 2004
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Teleflex Medical</b>
Location	Fall River, MA, US
Contact	SUSAN KAGAN
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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