

K190026 Arrow Epidural Needle KZ-05500-007(Luer)Aug 21, 2019
226 days to decisionK190026 · Product code: **BSP** · Anesthesiology
Source: <https://www.510kdatabase.net/k190026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Conduction, Anesthetic (w/wo Introducer) (BSP)
Date received	Jan 7, 2019
Decision date	Aug 21, 2019
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary
Other names	KZ-05500-009 (NRFit)

APPLICANT

Company	Teleflex Medical
Location	Fall River, MA, US
Contact	Lakshmi Kanuri
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...