FDA 510(k) Premarket Notification

CLEARED

Apr 25, 2018
187 days to decision

K173321 StimuQuik 21G x 9cm (3.5”) Peripheral Nerve Block Needle, StimuQuik Echo 21G x 9cm (3.5”) Peripheral Nerve Block Needle, StimuQuik 21G x 15cm (6”) Peripheral Nerve Block Needle, StimuQuik Echo 21G x 15cm (6”) Peripheral Nerve Block Needle, StimuQuik 21G x 2.5cm (1”) Peripheral Nerve Block Needle

K173321 · Product code: **BSP** · Anesthesiology
Source: https://www.510kdatabase.net/k173321/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Conduction, Anesthetic (w/wo Introducer) (BSP)
Date received	Oct 20, 2017
Decision date	Apr 25, 2018
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Teleflex Medical**
Location	Fall River, MA, US
Contact	Kristen Bisanz
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...