

**K941419 DISPOSABLE SPINAL INTRODUCER SHEATH**Jun 21, 1994  
90 days to decisionK941419 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k941419/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 23, 1994
Decision date	Jun 21, 1994
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Trimedynne, Inc.</b>
Location	Walker, MI, US
Contact	PETER HYDE
Website	<a href="http://www.trimedynne.com/">http://www.trimedynne.com/</a>
510(k) history	58 submissions · 58 cleared · 1981-2005

Trimedynne, Inc. is a manufacturer of Holmium:YAG lasers and surgical peripherals. The company specializes in laser-based surgical solutions for minimally invasive procedures across multiple specialties including urology, orthopedics, spine surgery, and general surgery. Trimedynne has received FDA 510(k) clearances from total submissions since its first clearance in 1981. The company's regulatory focus centers on General & Plastic Surgery devices, which represent 83% of its submission history. The latest clearance on record dates to 2005, reflecting the company's historical...

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