

**K992230 OMNITIP SIDE FIRING SWITCHABLE TIP WITH SUCTION/IRRIGATION, MODEL 20371-HP**Jul 12, 1999  
10 days to decisionK992230 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k992230/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 2, 1999
Decision date	Jul 12, 1999
Days to decision	10 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trimedyne, Inc.</b>
Location	Walker, MI, US
Contact	SUSAN H GAMBLE
Website	<a href="http://www.trimedyne.com/">http://www.trimedyne.com/</a>
510(k) history	58 submissions · 58 cleared · 1981-2005

Trimedyne, 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. Trimedyne 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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