

**K023535 TRIPTER X-1 COMPACT DUET**Jan 17, 2003  
88 days to decisionK023535 · Product code: **LNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k023535/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Oct 21, 2002
Decision date	Jan 17, 2003
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Direx Systems Corp.</b>
Location	Natick, MA, US
Contact	LARISA GERSHTEIN
510(k) history	22 submissions · 22 cleared · 2003-2012

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