

**K050091 TRIPTER-X1 COMPACT DUET SP (SEPARATED PULSE)**Mar 16, 2005  
61 days to decisionK050091 · Product code: **LNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k050091/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Jan 14, 2005
Decision date	Mar 16, 2005
Days to decision	61 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 GERSTEIN
510(k) history	22 submissions · 22 cleared · 2003-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050091/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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