

K053640 INTEGRAMar 1, 2006
61 days to decisionK053640 · Product code: **LNS** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Dec 30, 2005
Decision date	Mar 1, 2006
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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