

K062147 INTEGRA SLOct 20, 2006
85 days to decisionK062147 · Product code: **LNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k062147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Jul 27, 2006
Decision date	Oct 20, 2006
Days to decision	85 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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