

**K042427 GENESTONE EXEL (XL) EXTRACORPOREAL SHOCK  
WAVE LITHOTRIPTER**Dec 3, 2004  
86 days to decisionK042427 · Product code: **LNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k042427/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Sep 8, 2004
Decision date	Dec 3, 2004
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Genemed, Inc.</b>
Location	Middlebury, CT, US
Contact	DAVID BALZER
510(k) history	2 submissions · 2 cleared · 1994-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042427/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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