

**K101482 EM-9000**Mar 31, 2011  
307 days to decisionK101482 · Product code: **LNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k101482/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	May 28, 2010
Decision date	Mar 31, 2011
Days to decision	307 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elite Medical, Inc.</b>
Location	Atlanta, GA, US
Contact	STEVEN J DE BROCK
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101482/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 19, 2026