

**K042561 TWINHEADS TH-103 EXTRACORPOREAL SHOCK
WAVE LITHOTRIPTER**Oct 12, 2004
21 days to decisionK042561 · Product code: **LNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k042561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Sep 21, 2004
Decision date	Oct 12, 2004
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fmd, LLC
Location	Redmond, WA, US
Contact	YOUSRY FARAGALLA
510(k) history	2 submissions · 2 cleared · 2003-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042561/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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