

K121656 GEMINI LITHOTRIPTERSep 24, 2012
111 days to decisionK121656 · Product code: **LNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k121656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Jun 5, 2012
Decision date	Sep 24, 2012
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dornier Medtech America, Inc.
Location	Marietta, GA, US
Contact	JOHN HOFFER
510(k) history	40 submissions · 40 cleared · 1990-2023

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