

K221903 Delta III ProFeb 22, 2023
237 days to decisionK221903 · Product code: **LNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Jun 30, 2022
Decision date	Feb 22, 2023
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	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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