FDA 510(k) Premarket Notification

K221903 Delta III Pro

CLEARED

Feb 22, 2023
237 days to decision

K221903 · Product code: **LNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221903/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotriptor, 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