FDA 510(k) Premarket Notification

K170122 Delta III Lithotripter

CLEARED

Jun 28, 2017
166 days to decision

K170122 · Product code: **LNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k170122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotriptor, Extracorporeal Shock-wave, Urological (LNS)
Date received	Jan 13, 2017
Decision date	Jun 28, 2017
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dornier Medtech America**
Location	Kennesaw, GA, US
Contact	John Hoffer
510(k) history	6 submissions · 6 cleared · 2013-2025