FDA 510(k) Premarket Notification

K111947 DUET MAGNA

CLEARED

Mar 1, 2012
237 days to decision

K111947 · Product code: **LNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k111947/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotriptor, Extracorporeal Shock-wave, Urological (LNS)
Date received	Jul 8, 2011
Decision date	Mar 1, 2012
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Direx Systems Corp.**
Location	Natick, MA, US
Contact	LARISA GERSHTEIN
510(k) history	22 submissions · 22 cleared · 2003-2012