FDA 510(k) Premarket Notification

K050091 TRIPTER-X1 COMPACT DUET SP (SEPARATED PULSE)

CLEARED

Mar 16, 2005
61 days to decision

K050091 · Product code: **LNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k050091/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotriptor, Extracorporeal Shock-wave, Urological (LNS)
Date received	Jan 14, 2005
Decision date	Mar 16, 2005
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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