FDA 510(k) Premarket Notification

K901223 VACUUM ERECTION DEVICE (VED)

CLEARED

May 4, 1990
51 days to decision

K901223 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k901223/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Mar 14, 1990
Decision date	May 4, 1990
Days to decision	51 days
Third-party review	No

APPLICANT

Company	**Mission Pharmacal Co.**
Location	San Antonio, TX, US
Contact	GEORGE ALEXANDRIDES
510(k) history	3 submissions · 3 cleared · 1985-1995