FDA 510(k) Premarket Notification

K000124 SENSATION -VACUUM ASSIST DEVICES

CLEARED

Jul 10, 2000
174 days to decision

K000124 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k000124/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Jan 18, 2000
Decision date	Jul 10, 2000
Days to decision	174 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Prosurg, Inc.**
Location	San Jose, CA, US
Contact	LEE BUI
510(k) history	16 submissions · 16 cleared · 2000-2016