FDA 510(k) Premarket Notification

K980948 VED VALU- VACUUM ERECTION DEVICE

CLEARED

Jun 25, 1998
104 days to decision

K980948 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k980948/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Mar 13, 1998
Decision date	Jun 25, 1998
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mission Pharmacal Comp**
Location	New York, NY, US
Contact	ANDREW I SEALFON
510(k) history	1 submissions · 1 cleared · 1998-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k980948/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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