K981506 RESTORE VACUUM ERECTION DEVICE, CONFIDE VACUUM ERECTION DEVICE, PEP (PENILE ERECTION PROGRAM), RELY VACUUM ERECTION DEV)

CLEARED

Jun 25, 1998
59 days to decision

K981506 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k981506/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Apr 27, 1998
Decision date	Jun 25, 1998
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Repro-Med Systems, Inc.**
Location	Middletown, NY, US
Contact	ANDREW I SEALFON
510(k) history	6 submissions · 5 cleared · 1985-2011