

K981506 RESTORE VACUUM ERECTION DEVICE, CONFIDE VACUUM ERECTION DEVICE, PEP (PENILE ERECTION PROGRAM), RELY VACUUM ERECTION DEV)Jun 25, 1998
59 days to decisionK981506 · Product code: **LKY** · Gastroenterology & Urology
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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

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