

K971257 VTU-1 VACUUM ERECTION SYSTEMOct 3, 1997
182 days to decisionK971257 · Product code: **LKY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k971257/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Apr 4, 1997
Decision date	Oct 3, 1997
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mckenna & Cuneo
Location	Washington, DC, US
Contact	DONALD R STONE
510(k) history	3 submissions · 2 cleared · 1995-1997

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