

K012639 SE-300 VACUUM THERAPY SYSTEMNov 9, 2001
88 days to decisionK012639 · Product code: **LKY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k012639/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Aug 13, 2001
Decision date	Nov 9, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Vts, Inc.
Location	Newkirk, OK, US
Contact	DENNIS L BELL
510(k) history	5 submissions · 5 cleared · 1999-2001

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