

K003115 ACTIS ADJUSTABLE CONSTRICTION LOOPDec 19, 2000
78 days to decisionK003115 · Product code: **LKY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k003115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Oct 2, 2000
Decision date	Dec 19, 2000
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vivus, Inc.
Location	Mountain View, CA, US
Contact	CAROL D KARP
510(k) history	2 submissions · 2 cleared · 1996-2000

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