

K993143 VITALITY SYSTEMDec 27, 1999
97 days to decisionK993143 · Product code: **LKY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k993143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Sep 21, 1999
Decision date	Dec 27, 1999
Days to decision	97 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Soma Blue, Inc.
Location	Augusta, GA, US
Contact	JOHN M MITCHELL
510(k) history	2 submissions · 2 cleared · 1999-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993143/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 1, 2026