FDA 510(k) Premarket Notification

K993143 VITALITY SYSTEM

CLEARED

Dec 27, 1999
97 days to decision

K993143 · 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