

**K993142 ELITE CUSTOM**Dec 27, 1999  
97 days to decisionK993142 · Product code: **LKY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k993142/>**SUBMISSION DETAILS**

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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**

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

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