

K983438 MAX ITFeb 8, 1999
132 days to decisionK983438 · Product code: **LKY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k983438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Sep 29, 1998
Decision date	Feb 8, 1999
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dorea, Inc.
Location	Cairo, GA, US
Contact	RICHARD V MOSES, JR.
510(k) history	1 submissions · 1 cleared · 1999-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983438/> 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