FDA 510(k) Premarket Notification

K972353 ERCO-RIBBON

CLEARED

Oct 28, 1997
126 days to decision

K972353 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k972353/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Jun 24, 1997
Decision date	Oct 28, 1997
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ercons, Inc.**
Location	New York, NY, US
Contact	YAKOV ALTSHULER
510(k) history	6 submissions · 6 cleared · 1997-1999