FDA 510(k) Premarket Notification

K974196 MEGAVAC SYSTEM

CLEARED

May 12, 1998
186 days to decision

K974196 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k974196/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Nov 7, 1997
Decision date	May 12, 1998
Days to decision	186 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Barry J. Kaplan, Inc.**
Location	San Diego, CA, US
Contact	BARRY J KAPLAN
510(k) history	1 submissions · 1 cleared · 1998-1998