FDA 510(k) Premarket Notification

K864833 POS-T-VAC

CLEARED

Apr 10, 1987
122 days to decision

K864833 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k864833/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Dec 9, 1986
Decision date	Apr 10, 1987
Days to decision	122 days
Third-party review	No

APPLICANT

Company	**Ekc, Inc.**
Location	Monroe, LA, US
Contact	WALKER, M.D.
510(k) history	1 submissions · 1 cleared · 1987-1987