FDA 510(k) Premarket Notification

K896060 ERECTION INDUCER DEVICE (EID)

CLEARED

Mar 20, 1990
153 days to decision

K896060 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k896060/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Oct 18, 1989
Decision date	Mar 20, 1990
Days to decision	153 days
Third-party review	No

APPLICANT

Company	**Performance Medical, Inc.**
Location	Great Neck, NY, US
Contact	ALAN P SCHWARTZ
510(k) history	1 submissions · 1 cleared · 1990-1990