FDA 510(k) Premarket Notification

K896061 ERECTION DEVICE

CLEARED

Mar 7, 1990
140 days to decision

K896061 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k896061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Oct 18, 1989
Decision date	Mar 7, 1990
Days to decision	140 days
Third-party review	No

APPLICANT

Company	**Clyde Engineering Service**
Location	New Orleans, LA, US
Contact	ROBERT CLYDE
510(k) history	1 submissions · 1 cleared · 1990-1990