FDA 510(k) Premarket Notification

K905015 SURGITEK ERECTEK TM EXTERNAL ERECTION DEVICE

CLEARED

Dec 28, 1990
51 days to decision

K905015 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k905015/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Nov 7, 1990
Decision date	Dec 28, 1990
Days to decision	51 days
Third-party review	No

APPLICANT

Company	**Surgitek**
Location	Mchenry, IL, US
Contact	STEVE APERAVICH
510(k) history	29 submissions · 28 cleared · 1983-1995