FDA 510(k) Premarket Notification

K000194 DIGITAL INFLECTION RIGIDOMETER (DIR)

CLEARED

Apr 10, 2000
80 days to decision

K000194 · Product code: **LIL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k000194/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Penile Tumescence (LIL)
Date received	Jan 21, 2000
Decision date	Apr 10, 2000
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Uroan Xxi Electromedicina**
Location	Baleares, ES
Contact	VICTORIA GAYA
510(k) history	1 submissions · 1 cleared · 2000-2000