FDA 510(k) Premarket Notification

K875333 SURGITEK NPT MONITOR

CLEARED

Apr 13, 1988
105 days to decision

K875333 · Product code: **LIL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k875333/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Penile Tumescence (LIL)
Date received	Dec 30, 1987
Decision date	Apr 13, 1988
Days to decision	105 days
Third-party review	No

APPLICANT

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