FDA 510(k) Premarket Notification

K831251 TUMISENSOR 1524

CLEARED

Jun 3, 1983
46 days to decision

K831251 · Product code: **LIL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k831251/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Penile Tumescence (LIL)
Date received	Apr 18, 1983
Decision date	Jun 3, 1983
Days to decision	46 days
Third-party review	No

APPLICANT

Company	**Life-Tech Intl., Inc.**
Location	Walker, MI, US
510(k) history	68 submissions · 66 cleared · 1982-2000