FDA 510(k) Premarket Notification

K830158 OREXAS POTENTEST

CLEARED

Feb 7, 1983
20 days to decision

K830158 · Product code: **LIL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k830158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Penile Tumescence (LIL)
Date received	Jan 18, 1983
Decision date	Feb 7, 1983
Days to decision	20 days
Third-party review	No

APPLICANT

Company	**Orexas Medical Corp.**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1983-1983