FDA 510(k) Premarket Notification

K822099 BIOREM 2000

CLEARED

Aug 27, 1982
42 days to decision

K822099 · Product code: **LIL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k822099/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Penile Tumescence (LIL)
Date received	Jul 16, 1982
Decision date	Aug 27, 1982
Days to decision	42 days
Third-party review	No

APPLICANT

Company	**Biorem**
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1982-1984