FDA 510(k) Premarket Notification

K833454 BIOREM 3000 & 4000

CLEARED

Feb 21, 1984
146 days to decision

K833454 · Product code: **LIL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k833454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Penile Tumescence (LIL)
Date received	Sep 28, 1983
Decision date	Feb 21, 1984
Days to decision	146 days
Third-party review	No

APPLICANT

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