

K833454 BIOREM 3000 & 4000Feb 21, 1984
146 days to decisionK833454 · Product code: **LIL** · Gastroenterology & UrologySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k833454/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 3, 2026