

K822099 BIOREM 2000Aug 27, 1982
42 days to decisionK822099 · 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

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Device record: <https://www.510kdatabase.net/k822099/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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