

K981634 BIOCIRCUITS IOS PROSTATE SPECIFIC ANTIGEN (PSA) TEST CARTRIDGES, BIOCIRCUITS IOS PSA CONTROLS

Oct 13, 1998
158 days to decision

K981634 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k981634/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	May 8, 1998
Decision date	Oct 13, 1998
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biocircuits Corp.
Location	Sunnyvale, CA, US
Contact	SHEILA J RAMERMAN
510(k) history	8 submissions · 8 cleared · 1995-1998

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k981634/> 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 June 29, 2026