

**K033786 LUMINESCENT IMMUNOASSAY KIT FOR THE
DETECTION OF TESTOSTERONE IN SERUM AND SALIVA**Feb 27, 2004
85 days to decisionK033786 · Product code: JIT · Chemistry
Source: <https://www.510kdatabase.net/k033786/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Dec 4, 2003
Decision date	Feb 27, 2004
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ibl GmbH
Location	East Stroudsburg, PA, US
Contact	Gary Lehnus
510(k) history	6 submissions · 6 cleared · 2003-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033786/> 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