

K232317 UC-1800 Automatic Urine Analyzer, URIT 11FA Urine Reagent Strips, URIT 12FA Urine Reagent StripsApr 26, 2024
267 days to decisionK232317 · Product code: JIO · Chemistry
Source: <https://www.510kdatabase.net/k232317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood, Occult, Colorimetric, In Urine (JIO)
Date received	Aug 3, 2023
Decision date	Apr 26, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Urit Medical Electronic Co., Ltd.
Location	Great Neck, NY, US
Contact	Jiang Jun
510(k) history	2 submissions · 2 cleared · 2009-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Dylan Wu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232317/>; 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 May 14, 2026