

K221871 Healstone Accurate (TM) Drug of Abuse Urine Test Cup, Healstone Accurate (TM) Drug of Abuse Urine Test Cup RxAug 30, 2022
63 days to decisionK221871 · Product code: **NFT** · Toxicology
Source: <https://www.510kdatabase.net/k221871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Amphetamine, Over The Counter (NFT)
Date received	Jun 28, 2022
Decision date	Aug 30, 2022
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Healstone Biotech, Inc.
Location	Vancouver, CA
Contact	Bryan Fang
510(k) history	3 submissions · 3 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	Joe Shia

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/k221871/>; 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 26, 2026