

**K201630 AssureTech DOA Dipstick Screen Panel Tests,  
AssureTech DOA Integrated Cup Tests**Aug 12, 2021  
422 days to decisionK201630 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k201630/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jun 16, 2020
Decision date	Aug 12, 2021
Days to decision	422 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Assure Tech. (Hangzhou) Co, Ltd.</b>
Location	Hangzhou, CN
Contact	Shisheng Ling
510(k) history	7 submissions · 7 cleared · 2016-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Lsi International</b>
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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201630/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026