

**K151211 AssureTech Secobarbital Strip, AssureTech Oxycodone Strip, AssureTech Secobarbital/Oxycodone Panel Dip, AssureTech Secobarbital/Oxycodone Quick Cup, AssureTech Secobarbital/Oxycodone Turn Key-Split Cup**Jun 4, 2015  
29 days to decisionK151211 · Product code: DIS · Toxicology  
Source: <https://www.510kdatabase.net/k151211/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Enzyme Immunoassay, Barbiturate (DIS) |
| Date received         | May 6, 2015                           |
| Decision date         | Jun 4, 2015                           |
| Days to decision      | 29 days                               |
| Third-party review    | No                                    |
| Summary / Statement   | Summary                               |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Assure Tech. Co., Ltd.</b>         |
| Location       | Hangzhou, CN                          |
| Contact        | Eric Lin                              |
| 510(k) history | 3 submissions · 3 cleared · 2015-2016 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151211/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 3, 2026