

K152768 Assure Tech hCG Pregnancy Serum/Urine Combo Test Cassette, Assure Tech hCG Pregnancy Serum/Urine Combo Test Strip

Feb 24, 2016
153 days to decision

K152768 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k152768/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Sep 24, 2015
Decision date	Feb 24, 2016
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Assure Tech. Co., Ltd.
Location	Hangzhou, CN
Contact	ERIC LIN
510(k) history	3 submissions · 3 cleared · 2015-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152768/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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