

**K091714 ALCODIGITAL BREATHALYZER, MODEL AT576,  
AT577, AT578, AT579**Nov 18, 2009  
161 days to decisionK091714 · Product code: DJZ · Toxicology  
Source: <https://www.510kdatabase.net/k091714/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices, Breath Trapping, Alcohol (DJZ)
Date received	Jun 10, 2009
Decision date	Nov 18, 2009
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Skyfine Inc. Limited</b>
Location	Taipei County, TW
Contact	MICHAEL LEE
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091714/>; 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 22, 2026