

**K162698 MAGLUMI 2000 TSH, MAGLUMI 2000 Immunoassay Analyzer**Jul 14, 2017  
290 days to decisionK162698 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k162698/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Sep 27, 2016
Decision date	Jul 14, 2017
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen New Industries Biomedical Engineering Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Jie Rao
510(k) history	5 submissions · 5 cleared · 2017-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162698/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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