

**K192547 MAGLUMI 2000 HCG/ $\beta$ -HCG**Jan 17, 2020  
122 days to decisionK192547 · Product code: **DHA** · Chemistry  
Source: <https://www.510kdatabase.net/k192547/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Sep 17, 2019
Decision date	Jan 17, 2020
Days to decision	122 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/k192547/> 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 May 27, 2026