

**K242922 Extracorporeal Shock Wave Lithotripter (U200)**Jun 18, 2025  
267 days to decisionK242922 · Product code: **LNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k242922/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Sep 24, 2024
Decision date	Jun 18, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Wikkon Precision Technologies Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Jack Kong
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qimmiq Medical Consulting Service Co., Ltd.</b>
Contact	Yijie You

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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