

**K252464 Surgical Microscope (OMS2360, OMS2380)**Apr 28, 2026  
265 days to decisionK252464 · Product code: **NBL** · Dental  
Source: <https://www.510kdatabase.net/k252464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Fluorescence Caries Detection (NBL)
Date received	Aug 6, 2025
Decision date	Apr 28, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zumax Medical Co., Ltd.</b>
Location	Suzhou, CN
Contact	Alfred Hee
Website	<a href="https://www.zumaxmedical.com">https://www.zumaxmedical.com</a>
510(k) history	1 submissions · 1 cleared · 2026-2026

Zumax Medical Co., Ltd. is a medical device manufacturer with a manufacturing facility in Suzhou, China. The company specializes in surgical and diagnostic equipment for healthcare professionals. Zumax Medical has received FDA 510(k) clearance from total submission. The company's regulatory focus is Dental devices, with clearances spanning 2026. The company remains active, with its latest clearance in 2026. Explore the company's cleared device names, product codes, and clearance dates in the database.

**REGULATORY CONSULTANT**

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Consulting firm	<b>Suzhou Device Innovation Medical Consulting Co., Ltd.</b>
Contact	Mike Gu

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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