April 28, 2026

Zumax Medical CO., LTD
% Mike Gu
RA Director
Suzhou Device Innovation Medical Consulting Co., Ltd
Room 1001, Building 19, No. 3188 Renmin Road
Suzhou, Jiangsu 215000
CHINA

Re: K252464
Trade/Device Name: Surgical Microscope (OMS2360, OMS2380)
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser fluorescence caries detection device
Regulatory Class: Class II
Product Code: NBL, EPT
Dated: June 25, 2025
Received: August 6, 2025

Dear Mike Gu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252464

Device Name
Surgical Microscope

Indications for Use *(Describe)*
The surgical microscope is intended for use by qualified dental professionals in hospital operating rooms and hospital clinical settings to provide illumination and magnification of the surgical area and for the support of visualization in surgical procedures or examinations (except ophthalmic surgeries). It optionally enables handling of light curing dental composite resins and aids in reducing specular light reflections and enhances contrast between red tissue and blood. The fluorescence mode is intended for use by qualified dental professionals in hospital clinical settings as an adjunctive aid to assist in the detection of dental caries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K252464

Section 038: 510(k) Summary

Surgical Microscope

510(k) Summary

K number: K252464

I, Submitter Information

Name: Zumax Medical CO., LTD.
Address: 5 Zhiying Street, Suzhou New District, Suzhou, Jiangsu, China 215129
Telephone: +86-512-66650512-504
Fax: +86-512-66909655
Contact person: Alfred Hee
Email: alfred.hee@zumaxmedical.com

II, Date Prepared

June 30, 2025

III, Device Information

Trade name:	Fluorescence Mode
Common name:	Dental Fluorescence Examination Device
Regulation class:	Class II
Regulation number:	21 CFR 872.1745
Review Panel:	Dental
Product code:	NBL

IV, Predicative Device

510(k):	K171007
Device name:	Fluorescence Mode
Manufacturer:	Carl Zeiss Suzhou Co., Ltd

V, Device Description

Surgical microscopes OMS2360, OMS2380 can be installed in floor stand ceiling mounted, wall mounted and fixed ground. The installation methods are electrically identical, and the components include microscope main body, super balancing arm, second arm, and first arm, and the difference is that the installed structural parts are different.

The Fluorescence Mode is an accessory to the OMS2360, OMS2380 surgical microscope to utilize a kind of LED light that illuminates the tooth surfaces in the visible domain in the blue light region with wavelength 405nm.

VI, Indication for Use

The surgical microscope is intended for use by qualified dental professionals in hospital operating rooms and hospital clinical settings to provide illumination and magnification of the surgical area and for the support of visualization in surgical procedures or examinations (except ophthalmic surgeries). It optionally enables handling of light curing dental composite resins and aids in reducing specular light reflections and enhances contrast between red tissue and blood.
The fluorescence mode is intended for use by qualified dental professionals in hospital clinical settings as an adjunctive aid to assist in the detection of dental caries.

VII, Predicate Comparison

Table 1: Substantial Equivalence Table

Attribute	Subject device	Predicate device	Comments
510(k) number	Not applicable	K171007	/
Intended use	The surgical microscope is intended for use by qualified dental professionals in hospital operating rooms and hospital clinical settings to provide illumination and magnification of the surgical area and for the support of visualization in surgical procedures or examinations (except ophthalmic surgeries). It optionally enables handling of light curing dental composite resins and aids in reducing specular light reflections and enhances contrast between red tissue and blood. The fluorescence mode is intended for use by qualified dental professionals in hospital clinical settings as an adjunctive aid to assist in the detection of dental caries.	The Fluorescence Mode is intended to be used by dentist as an aid in the detection of dental caries.	Same
Indication for use	The surgical microscope is intended for use by qualified dental professionals in hospital operating rooms and hospital clinical settings to provide illumination and magnification of the surgical area and for the support of visualization in surgical procedures or examinations (except ophthalmic surgeries). It optionally enables handling of light curing dental composite resins and aids in reducing specular light	The Fluorescence Mode is intended to be used by dentist as an aid in the detection of dental caries.	Same

	reflections and enhances contrast between red tissue and blood. The fluorescence mode is intended for use by qualified dental professionals in hospital clinical settings as an adjunctive aid to assist in the detection of dental caries.		
Device Classification Name	Laser Fluorescence Caries Detection	Laser Fluorescence Caries Detection	Same
Generic Common Name	Dental Fluorescence Examination Device	Dental Fluorescence Examination Device	Same
Classification Product Code	NBL	NBL	Same
Class	II	II	Same
Intended user	No special requirements	No special requirements	Same
Technology	Fluorescence technology to aid in the detection of carious lesions	Fluorescence technology to aid in the detection of carious lesions	Same
Mode of Operation	Excites bacteria to fluoresce	Excites bacteria to fluoresce	Same
Detection Wavelength	405 nm	405 nm	Same
Device Operating Feature	Microscope with built-in feature provides visualization and an uninterrupted workflow	Dental microscope with built-in feature provides visualization and an uninterrupted workflow	Same
Light intensity	≥90,000 lx	97540 lx	Similar, analysis

<table>
<tr><th>Attribute</th><th>Subject device</th><th>Predicate device</th><th>Comments</th></tr>
<tr><td></td><td>(at the working distance of 200mm)</td><td>(at the working distance of 200mm)</td><td>1</td></tr>
<tr><td>theWorking distance</td><td>200-450 mm</td><td>200-430 mm</td><td>Similar, analysis 2</td></tr>
<tr><td>Power source</td><td>40VA</td><td>120VA</td><td>Similar, analysis 3</td></tr>
<tr><td>Environmental conditions</td><td>Ambient requirements for operation
<table><tr><th>Designation</th><th>Value</th></tr><tr><td>Temperature</td><td>+ 10°C ... +40°C</td></tr><tr><td>Rel. humidity</td><td>30% ... 75%</td></tr><tr><td>Air pressure</td><td>700 hPa ... 1060 hPa</td></tr></table>
Ambient requirements for transport and storage
<table><tr><th>Designation</th><th>Value</th></tr><tr><td>Temperature</td><td>- 40°C ... + 55°C</td></tr><tr><td>Rel. humidity</td><td>10% ... 80%</td></tr><tr><td>Air pressure</td><td>500 hPa ... 1060 hPa</td></tr></table></td><td>Ambient requirements for operation
<table><tr><th>Designation</th><th>Value</th></tr><tr><td>Temperature</td><td>+ 10°C ... +40°C</td></tr><tr><td>Rel. humidity</td><td>30% ... 75%</td></tr><tr><td>Air pressure</td><td>700 hPa ... 1060 hPa</td></tr></table>
Ambient requirements for transport and storage
<table><tr><th>Designation</th><th>Value</th></tr><tr><td>Temperature</td><td>- 40°C ... + 70°C</td></tr><tr><td>Rel. humidity</td><td>10% ... 90%</td></tr><tr><td>Air pressure</td><td>500 hPa ... 1060 hPa</td></tr></table></td><td>Similar, analysis 4</td></tr>
<tr><td>Standards</td><td>ISO 10936-1:2000
IEC 60601-2:2014
IEC 60601-1:2005
IEC 62471:2006
IEC 62366-1:2015
IEC 60601-1-6:2020
IEC80601-2-60:2019</td><td>ISO 10936-1:2000
IEC 60601-2:2014
IEC 60601-1:2005
IEC 62471:2006
IEC 62366-1:2015</td><td>Same</td></tr>
<tr><td>Software</td><td>Software of Surgical Microscope:
• Video Control (Only applicable to the video accessory which is optional before leaving the factory)</td><td>Software of Surgical Microscope:
• Light Source Control
• Filter Control
• Video Control
• Wi-Fi Module: Firmware processes network communication</td><td>Similar, analysis 5</td></tr>
</table>

Analysis 1: Test shows that the light intensity of the subject product is slightly higher than predicate one. The light source of the subject product and predicate product both meet the requirements of IEC 62471:2006/EN 62471: 2008 Photobiological safety of lamps and lamp systems. Also, the performance of the two products meet the requirements of ISO 10936- 1:2000 Optics and photonics – Operation microscopes – Part 1: Requirements and test methods.

The light source is intended for illumination of the surgical area, the difference in

light intensity does not affect the performance and clinical use.
Analysis 2: The working distance of the subject product contains and is better than predicate product. This difference does not affect the performance of the product.
Analysis 3: Compared with subject device and predicate device, there is a difference in the power of the devices, but both can drive the devices to achieve their respective functions. The difference does not affect the safety and effectiveness of the device.
Analysis 4: Compared with subject device and predicate device, there is a difference in the temperature for transport and storage. The difference does not affect the safety and effectiveness of the device.
Analysis 5: Software of the subject product is used to control the video, the light source and filter are controlled are mechanically controlled, and there is no wireless module in the subject device.

VIII, Non-clinical Performance Testing

- Light safety testing in accordance with IEC 62471:2006.
- Electrical safety Testing and EMC in accordance with IEC60601-1 and IEC60601-1-2.
- Performance test for the fluorescence mode base on surgical microscope in accordance with ISO 10936-1:2000.

Additionally Conducting a concurrence evaluation on a certain number of clinical images from the same phantom or patients and reporting the results. The results show the ability of the device to provide images with equivalent diagnostic capability to those of the cleared predicate devices.
The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences.

IX, Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.