May 21, 2025

HJY Smart Medical Device Co., Ltd.
John Chen, Ph.D.
Chairman & CEO
12F., No. 415, Sec. 4, Xinyi Rd., Xinyi Dist.,
Taipei, TW 11051
Taiwan

Re: K243429
Trade/Device Name: HJY VisualNext 3D Endoscopic Vision System (HDSES01 / HDSES301)
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: April 21, 2025
Received: April 21, 2025

Dear Dr. John Chen:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.05.21 14:20:13 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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)*
K243429

Device Name
HJY VisualNext 3D Endoscopic Vision System

Indications for Use *(Describe)*
HJY VisualNext 3D Endoscopic Vision System is intended for viewing internal surgical sites during general surgical procedures and for use in visualization of structures within the brain during neurological surgical procedures as well as for viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy.

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.

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510(k) Summary

1 Date of summary:	May 21, 2025
2 Submitter:	HJY Smart Medical Device Co., Ltd.
Address:	12F., No. 415, Sec. 4, Xinyi Rd., Xinyi Dist., Taipei City 11051, Taiwan
Phone:	+886-933-869246
Fax:	+886-2-2298-3287
Contact:	John Jiannyuh Chen, M.S., Ph.D. (john.chen@hjy-med.com)

3 Identification of the device:

Proprietary/Trade name:	HJY VisualNext 3D Endoscopic Vision System
Product code:	GWG
Regulation number:	882.1480
Regulation description:	Endoscope, Neurological
Device class:	II

4 Identification of the predicate device:

Predicate device name:	HJY VisualNext Endoscopic Vision System
Manufacturer:	HJY Smart Medical Device Co., Ltd.
Product code:	GWG
Regulation number:	882.1480
Device class:	II
510(k) number	K222735

5 Indications for Use

HJY VisualNext 3D Endoscopic Vision System is intended for viewing internal surgical sites during general surgical procedures and for use in visualization of structures within the brain during neurological surgical procedures as well as for viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy.

6 Device Description

The HJY VisualNext 3D Endoscopic Vision System is a system used for viewing internal surgical sites during neurosurgical procedures. The system consists of the following components:

- Endoscope Control Unit (ECU) (Model number: HDSES01)
- Endoscope (Model number: HDSE301)

The endoscope is physically connected via a 5m BNC coaxial cable to the Endoscope Control Unit (ECU). The Endoscope consists of 2 LED lamps and a CMOS camera with 2 sensors, embedded in the proximal end of a rigid metal arthroscope, which captures the image and transmits to and is processed by the Endoscope Control Unit (ECU), subsequently output to and presented on an external monitor. Images are recordable and markable for further analysis. The Endoscope Control Unit (ECU) is not connectable to intranet or internet.

7 Comparison of Technological Characteristics

Item	Subject device	Predicate device	Comment
Proprietary name	HJY VisualNext 3D Endoscopic Vision System	HJY VisualNext Endoscopic Vision System	
510(k) No.	K243429	K222735	
Indications for Use	HJY VisualNext 3D Endoscopic Vision System is intended for Viewing internal surgical sites during general surgical procedures and for use in visualization of structures within the brain during neurological surgical procedures as well as for viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy.	HJY VisualNext Endoscopic Vision System is intended for viewing internal surgical sites during general surgical procedures and for use in visualization of structures within the brain during neurological surgical procedures as well as for viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy.	Same
Type of use	Prescription Use	Prescription Use	Same
System components	Rigid endoscope, ECU	Rigid endoscope, ECU	Same
Light transmission	Light emitted from integrated LED at proximal end of endoscope insertion tube	Light emitted from integrated LED at proximal end of endoscope insertion tube	Same
Light source	Integrated LED	Integrated LED	Same
Image	Rigid rod lenses + CMOS imaging sensor in endoscope main body	Rigid rod lenses + CMOS imaging sensor in endoscope main body	Same

transmission			
Direction of view	0°	0°	Same
Field of view	120°	120°	Same
Depth of field	5-100 mm	5-100 mm	Same
Image resolution	Optical resolution: 800x800 pixels (HD imager) TV Lines: 667 LW/PH @ 15% MTF	Optical resolution: 800x800 pixels (HD imager) TV Lines: 667 LW/PH @ 15% MTF	Same
Image display	External monitor	External monitor	Same
2D / 3D Imaging	2D & 3D	2D only	Different The subject device has 2 sensors while the predicate device has only 1 sensor.
Recording attribute	Via USB-port	Via USB-port	Same
Insertion tube working length	180 mm	180 mm	Same
Insertion tube outer diameter	7.0 mm	5.0 mm	Different The subject device is wider than the predicate device.
Single use or Reusable	Single use	Single use	Same

8 Non-Clinical Testing

A series of performance tests were performed to assess the safety and effectiveness of HJY VisualNext 3D Endoscopic Vision System. All test results demonstrate that subject device meets the requirements of its pre-defined acceptance criteria and intended use.

- Sterility testing was completed in accordance with the FDA guidance document “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile”.
- Biocompatibility testing – The endoscope (Model number: HDSE301) is categorized as an externally communicating device with limited contact duration (<24 hours) with neural tissue/bone/dentin and blood (indirect contact through reabsorption of CSF into the venous system) in accordance with the FDA guidance document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.” The following biocompatibility endpoints were assessed in accordance with the methods specified in the FDA

biocompatibility guidance: cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, neurotoxicity, and hemocompatibility (indirect hemolysis). Test results demonstrated that all acceptance criteria were met, supporting a favorable biocompatibility profile for the subject device.

- Software validation (Enhanced Documentation Level) was completed in accordance with requirements specified in the FDA guidance document "Content of Premarket Submissions for Device Software Functions"
- Electromagnetic compatibility and thermal safety testing were completed in accordance with IEC60601-1, IEC60601-1-2 and IEC60601-2-18
- Photobiological safety testing of the lamp was completed in accordance with IEC 62471.
- Non-clinical performance testing was conducted to evaluate image quality and establish substantial equivalence to the predicate device throughout the subject device's entire shelf life. This comprehensive assessment included the following tests:

Test	Test Method Summary	Results
Bench Testing	The study assessed image quality and overall performance of both aged and non- aged subject devices with direct comparison to the predicate device to ensure long-term stability and comparability to the predicate device. Key parameters evaluated included: • Field of View (FOV) • Direction of View (DOV) • Depth of Field (DOF) • Optical Magnification • Distortion • Image Intensity Uniformity • Signal-to-Noise Ratio • Sensitivity • Resolution (MTF - Modulation Transfer Function).	Pass Both aged and non-aged subject devices met the predefined acceptance criteria, demonstrating consistent image quality metrics comparable to the predicate device**.**

Animal Study Testing	The study was conducted in a porcine animal model to evaluate the 3D visualization performance of the subject device compared to the 2D visualization of the predicate device in brain and spine procedures**.** Testing was performed with aged and non-aged subject devices and the predicate device to assess image quality to the following parameters: • Resolution • Illumination • Color Representation • Contrast • Noise The subject device was connected to the Sony LMD-2451MT 3D Monitor (K113203) to assess 3D visualization performance in comparison to the predicate device (2D visualization).	Pass The subject device provided clear and stable 3D visualization of brain and spine tissues across all tested conditions. Image quality parameters, including resolution, color representation, contrast, and noise, met the predefined acceptance criteria when compared to the predicate device. Testing also validated compatibility with the Sony LMD-2451MT 3D Monitor**.**

9 Conclusion

The results of non-clinical testing, demonstrate that the technological differences, between the subject and predicate device, do not raise different questions of safety or effectiveness. Based on the demonstrated identical intended use, similar technological characteristics and the evidence from all the performance testing, the subject VisualNext 3D Endoscopic Vision System is substantially equivalent to the predicate device HJY VisualNext Endoscopic Vision System (K222735).