July 28, 2023

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

Re: K222735
Trade/Device Name: HJY VisualNext Endoscopic Vision System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: June 28, 2023
Received: June 30, 2023

Dear Dr. John Jiannyuh 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2023.07.28 15:11:18 -04'00'

Adam Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K222735

Device Name
HJY VisualNext™ Endoscopic Vision System

Indications for Use *(Describe)*
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.

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.**

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# 510(k) Summary

**5.1 Type of submission:** Traditional

**5.2 Date of summary:** July 28, 2023

**5.3 Submitter:** HJY Smart Medical Device Co., Ltd.

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**Contact:** John Jiannyuh Chen, MS., Ph.D (john.chen@hjy-med.com)
**Job title:** Chairman & CEO

**5.4 Identification of the device:**

**Proprietary/Trade name:** HJY VisualNext™ Endoscopic Vision System
**Product code:** GWG
**Regulation number:** 882.1480
**Regulation description:** Endoscope, Neurological
**Review panel:** Neurology
**Device class:** II

**5.5 Identification of the predicate device:**

**Predicate device name:** QEVO System with KINEVO 900
**Manufacturer:** Carl Zeiss Meditec AG.
**Product code:** GWG
**Regulation number:** 882.1480
**Device class:** II
**510(k) number:** K170667

### 5.7 Indications for Use

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.

### 5.8 Device description

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

- Endoscope Control Unit (ECU) (Model number: HDSES01)
- Endoscope (Model number: HDSE201)

The endoscope is physically connected via a 5m BNC cable to the Endoscope Control Unit (ECU). The Endoscope consists of 2 LED lamps and a CMOS camera, 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.

### 5.9 Non-clinical testing

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

- Sterilization test
- Shelf life test
- Biocompatibility test
  - In vitro cytotoxicity test
  - Intracutaneous irritation study
  - Skin sensitization study
  - Acute Systemic Toxicity Study
  - Pyrogen study

  Test results performed in biocompatibility test reports demonstrated that subject device complies with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-23 and USP<151>.

- Software validation
- Electromagnetic compatibility and electrical safety
- Usability test
- Performance test

| Test | Test Method Summary | Results |
|---|---|---|
| **Field of view** (FOV) | **Test apparatus:** Goniometer (Möller-Wedel/Goniometer-Spectrometer II goniometer)<br>**Conditions:** Disposable endoscope and Endoscope Control Unit (ECU) in both non-aged and aged conditions<br>**Purpose:** To verify the characteristic of field of view of the subject device and compare to that of predicate device | **Results:**<br>1. Non-Aged:120.15 ± 0.2 degrees<br>2. Aged:120.41 ± 0.2 degrees<br>3. These two conditions passed pre-defined acceptance criteria.<br>**Discussion on SE:** The field of view of the subject device is larger than that of the predicate device. The difference in FOV does not raise different safety and effectiveness questions. |

| Test | Test Method Summary | Results |
|---|---|---|
| **Direction of view** | **Test apparatus:** High accuracy theodolite (Leica/TM5100A)<br>**Conditions:** Disposable endoscope and Endoscope Control Unit (ECU) in both non-aged and aged conditions<br>**Purpose:** To verify the characteristic of direction of view of the subject device and compare to that of predicate device | **Results:**<br>1. Non-Aged: 4.02 ± 0.2 degrees<br>2. Aged: 2.10 ± 0.2 degrees<br>3. These two conditions passed pre-defined acceptance criteria.<br>**Discussion on SE:** The accuracy of direction of view met the requirements by ISO 8600-1. Although the direction of view of the subject device is different from that of predicate device, the difference in DOV does not raise different safety and effectiveness questions. |
| **Optical magnification** | **Test apparatus:** two-dimensional ruler glass<br>**Conditions:** Disposable endoscope and Endoscope Control Unit (ECU) in both non-aged and aged conditions<br>**Purpose:** To verify the characteristic of optical Magnification of the subject device and determine if both non-aged and aged test results will pass the pre-defined performance criteria. | **Results:**<br>1. Non-Aged: 0.014@ 38 mm object distance<br>2. Aged: 0.013 @38 mm object distance<br>3. These two conditions passed pre-defined acceptance criteria.<br>**Discussion on SE:**<br>1. The predicate does not claim the optical magnification. |
| **Distortion** | **Test apparatus:** two-dimensional ruler glass<br>**Conditions:** Disposable endoscope and Endoscope Control Unit (ECU) in both non-aged and aged conditions<br>**Purpose:** To verify the characteristic of distortion of the subject device and determine if both non-aged and aged test results will pass the pre-defined performance criteria. | **Results:**<br>1. Non-Aged: Maximal distortion 22.7%<br>2. Aged: Maximal distortion 22.7%<br>3. These two conditions passed pre-defined acceptance criteria.<br>**Discussion on SE:**<br>1. The predicate does not claim the distortion. |

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| Test | Test Method Summary | Results |
|---|---|---|
| **Image intensity uniformity** | **Test apparatus:** Sphere-optics integration sphere.<br>**Conditions:** Disposable endoscope and Endoscope Control Unit (ECU) in both non-aged and aged conditions<br>**Purpose:** To verify the characteristic of the subjected device on image intensity uniformity and determine if both non-aged and aged test results will pass the pre-defined performance criteria. | **Results:**<br>1. Non-Aged: R:0.52 for Red, G:0.60 for Green, B:0.60 for Blue<br>2. Aged: R:0.60 for Red, G:0.61 for Green, B:0.65 for Blue<br>3. These two conditions passed pre-defined acceptance criteria.<br>**Discussion on SE:**<br>1. The predicate does not claim the image intensity uniformity. |
| **Signal-to-noise ratio** | **Test apparatus:** Sphere-optics integration sphere.<br>**Conditions:** Disposable endoscope and Endoscope Control Unit (ECU) in both non-aged and aged conditions<br>**Purpose:** To verify the characteristic of signal-to-noise ratio of images of the subject device and determine if both non-aged and aged test results will pass the pre-defined performance criteria. | **Results:**<br>1. Non-Aged: R:20.47 @101.88 average gray level, G:40.90 @102.88 average gray level, B:22.24 @ 99.54 average gray level<br>2. Aged: R:20.24 @117.82 average gray level, G:35.18 @109.38 average gray level, B:21.47 @111.34 average gray level<br>3. These two conditions passed pre-defined acceptance criteria.<br>**Discussion on SE:**<br>1. The predicate does not claim the signal-to-noise ratio of images.<br>The results indicate that the device will be as safe and as effective in terms of signal-to noise over the course of proposed shelf life. |
| **Sensitivity** | **Test apparatus:** optronic integrating sphere and Photo-Research/PR670 Spectro-radiometer<br>**Conditions:** Disposable endoscope and Endoscope Control Unit (ECU) in both non-aged and aged conditions | **Results:**<br>1. Non-Aged: Signal to noise ratio@0.9 cd/$m^2$ : R:10.9058, G:9.99283, B:13.0905<br>2. Aged: Signal to noise ratio@0.81 cd/$m^2$ : R:13.14, G:8.88, B:14.85<br>3. These two conditions passed pre-defined |

| Test | Test Method Summary | Results |
|---|---|---|
| | **Purpose:** To verify the characteristic of sensitivity of the subject device and determine if both non-aged and aged test results will pass the pre-defined performance criteria. | acceptance criteria.<br>**Discussion on SE:**<br>1. The predicate does not claim the sensitivity of images. |
| **Depth of field** | **Test apparatus:** diffusing reflective slant edge and external light source.<br>**Conditions:** Disposable endoscope and Endoscope Control Unit (ECU) in both non-aged and aged conditions<br>**Purpose:** To verify the characteristic of depth of field of the subject device and compare to that of predicate device. | **Results:**<br>1. Non-Aged: 5-100 mm<br>2. Aged: 5-100 mm<br>3. These two conditions passed pre-defined acceptance criteria.<br>**Discussion on SE:** The DOF is wider than the predicate, and the difference in DOF does not raise different safety and effectiveness questions. |
| **Image resolution** | **Test apparatus:** diffusing reflective slant edge and external light source.<br>**Conditions:**<br>1. Disposable endoscope and Endoscope Control Unit (ECU) in both non-aged and aged conditions<br>2. Measure MTF @ 20, 30 and 100 mm object distance<br>3. Determine image resolution in terms of TV lines at 15% MTF<br>**Purpose:** To verify the characteristic of spatial frequency response of the subject device and compare to that of predicate device. | **Results:**<br>1. Non-Aged: 52.6% on axis, 37.1% @ 0.6 FOV<br>2. Aged: 54.1% on axis, 44.8% @ 0.6 FOV<br>3. These two conditions passed pre-defined acceptance criteria.<br>4. For image resolution at 15% MTF, the results are 730 and 670 TV lines/mm, respectively for pre and post shelf- life testing.<br>**Discussion on SE:** The image resolution in terms of spatial frequency response of the subject device over the course of the proposed shelf life is similar to that of predicate (642 TV lines @ 15% MTF). The difference in resolution does not raise different safety and effectiveness questions. |

| Test | Test Method Summary | Results |
|---|---|---|
| **Working length** | **Test apparatus:** Digital Caliper<br>**Conditions:** only measure the working length of the Disposable endoscope<br>**Purpose:** To verify the working length of the endoscope and compare to that of predicate device. | **Results:**<br>1. Working length: 180.76 mm<br>2. It passed pre-defined acceptance criteria.<br>**Discussion on SE:** Although the working length of the subject device is longer than that of predicate, the difference in working length does not raise different safety and effectiveness questions. |
| **Outer Diameter** | **Test apparatus:** Outside Micrometer<br>**Conditions:** Only measure the outer diameter of the disposable endoscope<br>**Purpose:** To verify the outer diameter of the endoscope and compare to that of predicate device. | **Results:**<br>1. Outer diameter: 5.28 - 5.32 mm<br>2. It passed pre-defined acceptance criteria.<br>**Discussion on SE:** Although the outer diameter is wider than the predicate, the difference does not raise different safety and effectiveness questions. |
| **Image quality test utilizing a clinically relevant biological tissue model** | **Test set up:** Use a live pig model and conduct the animal testing following the GLP standard in an animal operating room of a facility accredited under AAALACi standards.<br>**Conditions:**<br>1. The non-aged and aged ECU units were used for brain and spinal surgery tests.<br>2. Six pieces of endoscopes each from non-aged and aged conditions were used for brain and spinal surgery, respectively, as indicated in the intended use of the subject device.<br>3. Test under three different levels of reducing light intensity conditions and working lengths, respectively.<br>4. Two cleared devices each for spine and brain were applied for comparing with non-aged and aged subject devices. | **Results**:<br>1. The image quality of the non-aged and aged subject device passed the pre-defined acceptance criteria for the intended use on brain and spine endoscopic surgery.<br>2. Based on multiple ANOVA model, there is no significant difference (P=0.569) in image quality between the non-aged and aged subject device over the proposed shelf life of endoscope and service life of ECU.<br>3. Based on the agreement test, the image quality of both the non-aged and aged subject devices was found to be comparable to that of the FDA-cleared comparator devices for both brain and spine endoscopy.<br>4. Considering the significant impact of light intensity on image quality during spine and brain endoscopy, along with the influence of working |

| Test | Test Method Summary | Results |
|---|---|---|
| | **Purpose:**<br>To verify subject device performance in terms of image quality under different light levels and working distances in a clinically relevant biological tissue model to support the device intended use and substantial equivalence to the predicate. | length on image quality during spine endoscopy, it is crucial to exercise caution when utilizing the subject device under worse-case clinical use conditions, such as extreme light intensity or working lengths. Based on the statistical analysis, surgeons should be mindful of avoiding higher light intensity settings during brain and spine endoscopy and refrain from employing long working lengths during spine endoscopy procedures. Light intensity level is adjustable with the subject device as well as the predicate.<br><br>**Discussion on SE:**<br>1. Compared to cleared device, the quality image of subject device is similar to FDA cleared devices for the intended use of endoscopic application on brain and spine.<br>2. Based on the results, the subject device is as safe and as effective to the predicate on image quality. |

All the test results demonstrate HJY VisualNext™ Endoscopic Vision System meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

### 5.10 Clinical testing

No clinical test data was used to support the decision of substantial equivalence.

### 5.11 Substantial equivalence determination

HJY VisualNext™ Endoscopic Vision System submitted in this 510(k) file is substantially equivalent to the predicate device. Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

| Item | Subject device | Predicate device | Substantial equivalence determination |
|---|---|---|---|
| **Proprietary name** | HJY VisualNext™ Endoscopic Vision System | QEVO System with KINEVO 900 | |
| **510(k) No.** | K222735 | K170667 | |
| **Intended use** | 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. | The QEVO System with KINEVO 900 is intended for viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and 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. | Equivalence.<br>Although the wording on intended use between the subject device and the predicate is slightly different, it doesn't raise any new issues of substantial equivalence. |
| **Type of use** | Prescription Use | Prescription Use | Equivalence |
| **System components** | Rigid endoscope, ECU | Rigid endoscope, ECU | Equivalence |
| **Light transmission** | Light emitted from integrated LED at proximal end of endoscope insertion tube | Light source in endoscope main body, light transmission through insertion tube via fiber optics | Similar.<br>The difference doesn't raise any new issues of substantial equivalence. |
| **Light source** | Integrated LED (Intensity adjustable) | Integrated LED (Intensity adjustable) | Equivalence |

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| Item | Subject device | Predicate device | Substantial equivalence determination |
|---|---|---|---|
| **Proprietary name** | HJY VisualNext™ Endoscopic Vision System | QEVO System with KINEVO 900 | |
| **510(k) No.** | K222735 | K170667 | |
| **Image transmission** | Rigid rod lenses + CMOS imaging sensor in endoscope main body | Rigid rod lenses + CMOS imaging sensor in endoscope main body | Equivalence |
| **Direction of view** | 0° | 45° | Different. The difference doesn't raise any new issues of substantial equivalence. |
| **Field of view** | 120° | 100° | |
| **Depth of field** | 5-100 mm | 5-30 mm | |
| **Image resolution** | Optical resolution: 800x800 pixels (HD imager) TV Lines: 667 LW/PH @ 15% MTF | Optical resolution: 2 Mega Pixel (Full HD imager) TV lines: 642 TV lines at 15% MTF | Similar. The difference doesn't raise any new issues of substantial equivalence. |
| **Image display** | External monitor | External monitor | Equivalence |
| **2D / 3D Imaging** | 2D only | 2D only | Equivalence |
| **Recording attribute** | Via USB-port | Via USB-port | Equivalence |
| **Insertion tube working length** | 180 mm | 120 mm | Different. The subject device is longer than the predicate device. It doesn't raise any new issues of substantial equivalence. |
| **Insertion tube outer diameter** | 5.0 mm | 3.6 mm | Different. The subject device is wider than the predicate device. It doesn't raise any new issues of substantial equivalence. |
| **Single use or Reusable** | Single use | Reusable | Different. The difference doesn't raise any new issues of |

| Item | Subject device | Predicate device | Substantial equivalence determination |
|---|---|---|---|
| **Proprietary name** | HJY VisualNext™ Endoscopic Vision System | QEVO System with KINEVO 900 | |
| **510(k) No.** | K222735 | K170667 | |
| | | | substantial equivalence. |
| **Electrical safety** | IEC60601-1, IEC60601-1-2 and IEC60601-2-18 compliant | IEC60601-1, IEC60601-1-2 and IEC60601-2-18 compliant | Equivalence |

### 5.12 Similarity and difference

The HJY VisualNext™ Endoscopic Vision System has been compared with the QEVO System with KINEVO 900 (K170667). The subject device has the similar intended use, type of use, system components, light transmission, image transmission and image display as the predicate devices.

Although the direction of view, field of view, depth of field, image resolution, insertion tube working length and insertion tube outer diameter are different between the subject device and predicate devices, a series of tests were conducted and results demonstrated that the differences do not raise any new issue of substantial equivalence.

The subject device has undergone a series of testing, and the results passed the acceptance criteria defined by the testing standard used; Therefore, the differences between the subject device and the predicate device do not raise any new issues on safety and effectiveness. The subject device is substantially equivalent to the predicate devices as it claims.

### 5.13 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that HJY VisualNext™ Endoscopic Vision System is substantially equivalent to the predicate device.