March 20, 2020

enlightenVue, Inc.
Giacomo Basadonna
1111 Race Street, Suite 6a
Denver, Colorado 80206

Re: K192300
Trade/Device Name: enlightenVue Microendoscopy System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 21, 2020
Received: February 25, 2020

Dear Giacomo Basadonna:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192300

Device Name
enlightenVue Microendoscopy System

Indications for Use *(Describe)*
The enlightenVue Microendoscopy System is intended for visualization of body cavities, hollow organs, and canals. The surgiVue microendoscope is designed to be introduced through natural body cavities or surgical incisions through introducers, trocars, needles, sheaths, or other devices with lumens having inside diameters larger than the outer diameter of the microendoscope.

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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5.0

510(k) Summary (K192300) for the enlightenVue Microendoscopy System (per 21CFR 807.87(h))

1. SUBMITTER/510(K) HOLDER

enlightenVue
1111 Race Street, Suite 6a
Denver, CO 80206

Contact Person: Giacomo Basadonna M.D.
Telephone: 202-427-5177

Date Prepared: March 19, 2020

2. DEVICE NAME

Proprietary Name: enlightenVue Microendoscopy System
Common/Usual Name: Endoscope
Classification Name: Endoscope

3. PREDICATE DEVICE

Galileo Disposable Endoscope (K981928)

4. DEVICE DESCRIPTION

The enlightenVue Microendoscopy System is comprised of the surgiVue microendoscope and surgiTrac laser light source. This system is used to provide imaging capability of internal anatomy for both diagnostic and interventional procedures. The small laser light source focuses light onto a small fiber in the form of white light. The surgiTrac interfaces with the disposable surgiVue microendoscope and a PC to allow for illumination of the captured image.

5. INTENDED USE

The enlightenVue Microendoscopy System is intended for visualization of body cavities, hollow organs, and canals. The surgiVue microendoscope is designed to be introduced through natural body cavities or surgical incisions through introducers, trocars, needles, sheaths, or other devices with lumens having inside diameters larger than the outer diameter of the microendoscope.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The enlightenVue Microendoscopy System is substantially equivalent in function, and intended use to the predicate, the Galileo Disposable Endoscopes, subject of K981928.

The intended use of the enlightenVue Microendoscopy System and the predicate device is identical in that they are all indicated for visualization of body cavities, hollow organs, and canals. They are designed to be introduced through natural body cavities or surgical incisions through introducers, trocars, needles, sheaths, or other devices with lumens having inside diameters larger than the outer diameter of the endoscopes.

The technological characteristics of the enlightenVue Microendoscopy System and the predicate device are identical in that they both offer a channel for either viewing body cavities, tissues, organs, or canals and an optional channel for passing instruments or fluids into the desired anatomical sites. Both devices are provided sterile and intended for single use only. The devices are different in that the subject device includes an expandable tip, two accessory channels, a light source, and a camera. A reference device is used for comparison to validate the technological differences.

Table 1, on the next page, compares the subject device with the predicate.

Table 1: Side-by-Side Comparison of enlightenVue Microendoscopy System with Predicate Device

PRODUCT CHARACTERISTICS	ENLIGHTENVUE MICROENDOSCOPY SYSTEM	PREDICATE GALILEO DISPOSABLE ENDOSCOPE
Intended Use	The intended use of the enlightenVue Microendoscopy System is intended for the visualization of body cavities, hollow organs, and canals. It is also designed to be introduced through natural body orifices cavities or surgical incisions through introducers, trocars, needles, sheaths, or other devices with lumens having inside diameters larger than the outer diameter of the endoscope	
Product Code	GCJ	GCJ
Classification	Class II	Class II
Materials	surgiVue: Polypropylene Impact Copolymer, Polyimide, Pebax 7233, Pebax 5533, Pebax 3533, Nylon, Polysulfone, Polyester, Polymethylmethacrylate Fluorinated Polymer, Stainless Steel, Polycarbonate, Polyolefin, Pebax 4033, ABS, Polyvinylidene Fluoride	N/A
Reusable or Disposable	Disposable	Disposable
Light Source	Class 3R Laser	External
Field of View	120°	40°-70°
Direction of View	90°	0°-30°
Biocompatible	Yes	Yes
Sterilization Method	EtO	EtO
Accessories	Accessory tools with a maximum diameter of 1.0mm can be used in conjunction with the white instrument channel female luer. Active endoscopic accessories, such as laser probes and electrosurgical equipment may not be used in conjunction with the enlightenVue Microendoscopy System.	N/A
Regulatory Status	K192300	K981928

7. PERFORMANCE TESTING

Biocompatibility, packaging, mechanical and functional testing demonstrate that the enlightenVue Microendoscopy System is biocompatible and mechanically and functionally similar to the predicate device. The following tests have been performed:

- Accelerated Aging, 6 and 12 months
- Real-Time Aging, 3 months
- Shelf life Verification
- Cytotoxicity Test
- Irritation Test
- Sensitization Test
- Verification Test: PEMS System, Video System
- Verification Test: PEMS System
- Verification Test: PEMS System, FPGA
- Dimensional Verification
    - Cable Length
    - Working Length
    - Working Diameter
    - Secondary Channel Color and Symbol
    - Working Channel Color and Symbol
    - Handpiece Gap
    - Heat Shrink
    - Sharp Edges
- Verification Test: surgiTrac
    - Physical Characteristics
    - Electrical Characteristics
    - Safety Features
    - Functional Characteristics
    - Video System Communications
    - Video Stream
- Functional Verification: surgiVue Microendoscope
    - Cameral Specifications
    - Endoscope functionality
    - Endoscope Strength and Durability
    - Serialization Check Test
    - Radiant Power Distribution Test
    - Secondary Channel Camera Rinse Test
    - Water Ingress Test
- Usability Testing

- Laser Safety Testing

Evaluations were performed to determine the material and mechanical characteristics of the enlightenVue Microendoscopy System according to FDA recognized standards. In conclusion, the functional verification and validation testing have been performed which demonstrate that enlightenVue Microendoscopy System functions as intended and is safe and effective for its intended use.

8. CONCLUSION

The subject device is substantially equivalent to the predicate device. These conclusions are based upon the facts that the subject device is identical in intended use to the predicate, extensive validation testing was performed, and a reference device is used for comparison to validate different technological characteristics – the camera and light source – to the subject device. Any differences do not raise new types of questions of safety and effectiveness.