November 17, 2023

IQ Endoscopes Limited
Chris Jenkins
Head of Quality, Regulatory and Compliance
Basepoint Business Centre, Riverside Court Beaufort Park Way
Chepstow, Monmouth NP16 5UH
United Kingdom

Re: K232028
Trade/Device Name: Q Vision Sterile Single Use Adult Flexible Gastroscope (G-100); Q Base Reusable Base Unit (Q-100)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FET
Dated: July 7, 2023
Received: July 7, 2023

Dear Chris Jenkins:

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.

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
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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)*
K232028

Device Name
Q Vision Sterile Single Use Adult Flexible Gastroscope (G-100); Q Base Reusable Base Unit (Q-100)

Indications for Use *(Describe)*
IQ Endoscope's Gastroscope is intended to provide a live video stream in the upper gastrointestinal (GI) tract of adult patients to facilitate diagnosis of conditions in a clinical setting. The device contains a working channel which facilitates the capability to perform diagnostic/ therapeutic procedures of the upper GI tract. The device is sterile and single use and is not intended on being reprocessed.

IQ Endoscope's Q Base Q-100 Base Unit is designed to be used with IQ Endoscope's Q Vision G-100 Gastroscope and other ancillary equipment (e.g. medical grade video monitor) for endoscopy and endoscopic surgery within the upper digestive tract.
IQ Endoscope's Q Base Q-100 Unit is a reusable device intended to provide compressed air, power, and data connectivity to IQ Endoscope's Q Vision G-100 Gastroscope to facilitate diagnosis of conditions in a clinical setting.

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.

510(k) Summary Update

Contact Details (21 CFR 807.92(a)(1))

Applicant Name: IQ Endoscopes Limited
Applicant Address: Basepoint Business Centre, Riverside Court Beaufort Park Way, Chepstow, Monmouth NP16 5UH United Kingdom
Applicant Contact Telephone: +44 7828847591
Applicant Contact: Mr. Chris Jenkins
Applicant Contact Email: chris@iqendoscopes.co.uk

Device Name (21 CFR 807.92(a)(2))

Device Trade Name: Q Vision Sterile Single Use Adult Flexible Gastroscope (G-100); Q Base Reusable Base Unit (Q-100)
Common Name: Endoscope and accessories
Classification Name: Gastroscope And Accessories, Flexible/Rigid
Regulation Number: 876.1500
Product Code: FDS

Legally Marketed Predicate Devices (21 CFR 807.92(a)(3))

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172916	FUJIFILM Endoscope Model EG-760R	FDS
K163675	FUJIFILM Processor VP-7000 and Light source BL-7000	FET

Device Description Summary (21 CFR 807.92(a)(4))

The G-100 Gastroscope is only intended on being used with the Q-100 Base Unit. A description of the two devices and their functions can be found below:

IQ Endoscope's gastroscope is intended to provide a live video stream in the upper gastrointestinal (GI) tract of adult patients to facilitate diagnosis of conditions in a clinical setting. The device contains a working channel which facilitates the capability to perform diagnostic/ therapeutic procedures of the upper GI tract. The device is sterile and single use and is not intended on being reprocessed.

The G-100 Gastroscope is a flexible trans-orally introduced gastroscope which can be used to examine the oesophagus, stomach and the first and second parts of the duodenum using a live video feed from the Q-100 Base Unit. The device contains a working channel which facilities the capability to perform diagnostic and therapeutic procedures where indicated. Additionally, the device features water, air and suction channels to provide water, insufflate with air, and removal of debris as required during the endoscopy procedure. A water jet also allows the clinician to clear the distal tip lens of debris to ensure continued visualisation of the gastrointestinal tract throughout the procedure.

IQ Endoscope's Q Base Q-100 Base Unit is designed to be used with IQ Endoscope's Q Vision G-100 Gastroscope and other ancillary equipment (e.g. medical grade video monitor) for endoscopy and endoscopic surgery within the upper digestive tract.

IQ Endoscope's Q Base Q-100 Base Unit is a reusable device intended to provide compressed air, power, and data connectivity to IQ Endoscope's Q Vision G-100 Gastroscope to facilitate diagnosis of conditions in a clinical setting. The device connects air, power and data circuits to the G-100 gastroscope through a proprietary quick connector. The device connects to a 3rd party sterile water for irrigation and a visual display through an HDMI or BNC connection. The device may connect to a 3rd party data capture and storage accessory through an BNC connection for video and programmable on/off momentary button inputs.

Accessories required for the devices to function are listed below:

1. Vacuum source set between -40kPa and -55kPa.
2. Medical grade monitor with a resolution of at least 1920x1080 px and a monitor size of at least 22" with HDMI or HD-SDI inputs.
3. Image capture reporting and/or writing station.
4. BAXTER UKF7114 Sterile Water for irrigation

Intended Use/Indications for Use (21 CFR 807.92(a)(5))

IQ Endoscope's Gastroscope is intended to provide a live video stream in the upper gastrointestinal (GI) tract of adult patients to facilitate diagnosis of conditions in a clinical setting. The device contains a working channel which facilitates the capability to perform diagnostic/ therapeutic procedures of the upper GI tract. The device is sterile and single use and is not intended on being reprocessed.

IQ Endoscope's Q Base Q-100 Base Unit is designed to be used with IQ Endoscope's Q Vision G-100 Gastroscope and other ancillary equipment (e.g. medical grade video monitor) for endoscopy and endoscopic surgery within the upper digestive tract.

IQ Endoscope's Q Base Q-100 Unit is a reusable device intended to provide compressed air, power, and data connectivity to IQ Endoscope's Q Vision G-100 Gastroscope to facilitate diagnosis of conditions in a clinical setting.

Indications for Use Comparison (21 CFR 807.92(a)(5))

The indications for use statements for the IQ Endoscope system (subject) devices, namely the:

- IQ Endoscope 'G-100' Gastroscope
- IQ Endoscope 'Q-100' Base Unit are by comparison the same as those of the predicate system devices namely;
- FUJIFILM Upper gastrointestinal endoscope Model EG-760R - (K172916)
- FUJI VP-7000 Video Processor (K163675)

The subject and predicate gastroscopes are both intended for the 'visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum'.

The subject and predicate video processor base units are designed to be used with endoscopes, and endoscopic devices and accessories, during endoscopic examinations.

Technological Comparison (21 CFR 807.92(a)(6))

A comparison between the technical characteristics for the IQ Endoscope (subject) system devices, namely the:

- IQ Endoscopes Ltd 'G-100' Gastroscope
- IQ Endoscopes Ltd 'Q-100' Base Unit

And those of the predicate system devices namely;

- FUJIFILM Upper gastrointestinal endoscope Model EG-760R - (K172916)
- FUJI VP-7000 Video Processor (K163675)

is provided below.

Gastroscope:
Predicate Device: The FUJIFILM Upper gastrointestinal endoscope Model EG-760R
The FUJIFILM Upper gastrointestinal endoscope Model EG-760R, as stated in 510(k) K172916, is comprised of three general sections: a control portion, an insertion portion, and an umbilicus.

The control portion controls the angulation of the endoscopes. This portion also controls the flexibility of the distal end in the endoscopes.

The insertion portion contains glass fiber bundles, several channels, and a complementary metal–oxide– semiconductor (CMOS) image sensor in its distal end.
The channels in the insertion portion assist in delivering air/suction as well as endoscope accessories, such as forceps.
The glass fiber bundles allow light to travel through the endoscope and emit light from the tip of the insertion portion to illuminate the body cavity. This provides enough light to the CMOS image sensor to capture an image and display it on the monitor.
The umbilicus consists of electronic components needed to operate the endoscope when plugged in to the video processor and the light source.

The FUJIFILM Upper gastrointestinal endoscope Model EG-760R, as stated in 510(k) K172916, has been subjected to the bench performance testing as below and met pre-determined acceptance criteria in compliance with the following relevant standards:

Electrical safety:
- ANSI/AAMI ES60601-1:2012, - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2007, - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-6:2013, - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-18:2009 - Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Biocompatibility
- ISO 10993-1:2009 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Endoscope specific testing
- ISO 8600-1: 2015 - Medical endoscopes and endotherapy devices -- Part 1: General requirements
- ISO 8600-3:1997 - Endoscopes - Medical endoscopes and endotherapy devices Part 3: Determination of field of view and direction of view of endoscopes with optics.
- ISO 8600-4: 2014 - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion

The endoscopes met performance specifications in the following additional testing: (Testing standard not defined in the 510(k) - however is defined in Fuji Catalogue 2019 - ADVANCING DEEPER INSIGHTS IN ENDOSCOPY
- Field of view
- Bending capability
- Rate of suction
- Working length
- Diameter of forceps channel
- Viewing direction
- LG output
- Flexibility adjustment mechanism

Subject Device: The IQ Endoscopes Ltd. - Upper gastrointestinal endoscope Model No. 'G-100'
The IQ Endoscopes Ltd. - Upper gastrointestinal endoscope Model No. 'G-100' is comprised of three general sections: a control portion, an insertion portion, and an umbilicus.
The control portion controls the angulation of the endoscopes. This portion also controls the flexibility of the distal end in the endoscopes.

The insertion portion contains several channels, and a complementary metal–oxide–semiconductor (CMOS) image sensor in its distal end.
The channels in the insertion portion assist in delivering air/suction as well as endoscope accessories, such as forceps.
LEDs placed at the distal tip emit light from the tip of the insertion portion to illuminate the body cavity. This provides enough light to the CMOS image sensor to capture an image and display it on the monitor.
The umbilicus consists of electronic components needed to operate the endoscope when plugged in to the video processor and the light source.
Performance testing:
The IQ Endoscopes Ltd. Upper gastrointestinal endoscope Model No. 'G-100, has been subjected to the bench performance testing as below and met pre-determined acceptance criteria in compliance with the following relevant standards:

Electrical safety:
- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance
- IEC 60601-1-2:2014, - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-6:2013, - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-18:2009 - Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Biocompatibility
- ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021 - Biological Evaluation of Medical Devices - Part 23, Tests for Irritation
- ISO 10993-11:2017 - Biological evaluation of medical devices - Part 11, Tests for systemic toxicity
- USP 43 <151> Pyrogen test, 2020 & ISO 10993-11:2017

Endoscope specific testing
- ISO 8600-1: 2015 - Medical endoscopes and endotherapy devices -- Part 1: General requirements
- ISO 8600-3:2019 - Endoscopes - Medical endoscopes and endotherapy devices Part 3: Determination of field of view and direction of view of endoscopes with optics.
- ISO 8600-4: 2014 - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion

Other:
- IEC 62471 First edition 2006-07 – Photobiological Safety of Lamps and Lamp Systems.

The endoscopes met performance specifications in the following additional bench testing applied by IQ Endoscopes Ltd.
- Bending capability
- Rate of suction
- Working length
- Diameter of forceps channel
- Viewing direction

Discussion on the technical differences between the devices:
Difference 1: The predicate device uses glass-fiber bundles to transmit light from a required light source accessory to the distal tip of the endoscope so as to illuminate the surgical field in use. The new IQ Endoscope device has an integrated LED in the distal tip eliminating the need for an additional light source accessory.

Difference 2: The predicate is designed and indicated as a reusable device, whereas the new IQ Endoscope device is designed and indicated for single use only.
Difference 3: The new G-100 has 3 valves and only one button function.
Difference 4: Fujifilm has access ports to allow decontamination.
Difference 5: The predicate features LG output and flexibility adjustment mechanism, whereas the new IQ Endoscope device features LEDs in the distal tip and no flexibility adjustment mechanism respectively.

Video Processor / Base Unit:
Predicate Device: The FUJIFILM VP-7000 Video Processor
The VP-70000 Video Processor relays the image from the endoscope to a video monitor. Projection can be either analog or digital at the user's preference. The Processor incorporates internal or external digital
storage capacity. The Processor also controls the light projected to the body cavity. The Processor provides for optional structural enhancement through user modes FICE, BLI, BLI-bright and LCI. Spectral and structural enhancements are achieved through proprietary software. The device is AC operated at a power setting of 100-240V/50-60Hz/0.8-0.5A. The Processor is housed in a steel - polycarbonate
case measuring 390x110x485mm.
The DK-7000E Keyboard is a standard accessory of VP-7000. It is used to enter pertinent procedural information (patient, physician, date, etc.) for display on the video monitor and digital/analog storage systems. The Keyboard is also used to control operational features of the VP-7000 Processor. The Keyboard resembles a standard computer keyboard, and is provided with an instruction label attached to it.
Non-Clinical testing of the VP-70000 consisted of:
- Software validation in accordance with IEC 62304
- Electrical safety in accordance with IEC 60601 requirements.
- Functional testing of the FICE, BLI, BLI-bright and LCI image processing features included Contrast Enhancement (or Color and Contrast Enhancement), Resolving Power, Noise, Artifact Creation, and Color Reproduction.

Clinical testing of the VP-70000 consisted of:
The BLI and BLI-bright features were evaluated in a prospective clinical trial to objectively assess the overall image quality of each of the BLI and BLI-bright presets in comparison to the FICE presets (K140149).

Subject Device: The IQ Endoscopes Ltd. 'Q-100' base unit
The IQ Endoscopes Ltd. - 'Q-100' base unit is an endoscopic video imaging system that:
- Receives video signals from the connected endoscope,
- Controls the light at the endoscope tip, and outputs the video signal to a connected external video monitor.
- Provides signals to capture images by a connected external image capturing system.
- contains an air pressure powered pump to provide water for the endoscope lens washing function, and to supply air for insufflation through the endoscope.
Comparison of Technical Characteristics:
Common technical features:
- Video outputs for connection to medical grade monitors.
- Data cable outputs for connection to image capture devices

Technical variances:
Difference 1: The predicate has a graphical user interface and operational menu and therefore incorporates software, whereas the 'IQ Endoscopes Ltd. 'Q-100' base unit does not incorporate software and therefore does not have a user menu.
Difference 2: The predicate provides for image processing enhancement termed as "BLI" (Blue Light Imaging) and LCI (Linked Color Imaging) through user of proprietary software, whereas the IQ Endoscopes Ltd. 'Q-100' base unit does not incorporate software and therefore does not have such features.
Difference 3: The predicate requires use of a specific keyboard accessory for functionality, whereas the IQ Endoscopes Ltd. 'Q-100' base unit does not.

Difference 4: The predicate requires use of an external fiber bundle light source accessory to transmit light to the body cavity, whereas the IQ Endoscopes Ltd. 'Q-100' base unit has an inbuilt LED light source.

Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b))

The non-clinical testing performed upon the IQ Endoscope model No. 'G-100' and base unit Model 'Q-100' is as listed below:

Electrical safety:
- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance
- IEC 60601-1-2:2014, - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-6:2013, - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-18:2009 - Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Biocompatibility
- ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021 - Biological Evaluation of Medical Devices - Part 23, Tests for Irritation
- ISO 10993-11:2017 - Biological evaluation of medical devices - Part 11, Tests for systemic toxicity
- USP 43 <151> Pyrogen test, 2020 & ISO 10993-11:2017

Endoscope specific testing
- ISO 8600-1:2015 - Medical endoscopes and endotherapy devices -- Part 1: General requirements
- ISO 8600-3:2019 - Endoscopes - Medical endoscopes and endotherapy devices Part 3: Determination of field of view and direction of view of endoscopes with optics.
- ISO 8600-4:2014 - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion

Other:
- IEC 62471 First edition 2006-07 – Photobiological Safety of Lamps and Lamp Systems
- ISO 15739: 2017 - Photography — Electronic still-picture imaging — Noise measurements.
- ISO 14524: 2009 - Photography — Electronic still-picture Cameras — Methods for measuring optoelectronic conversion functions (OECFs).
- ISO 12233: 2017 - Photography — Electronic still picture imaging — Resolution and spatial frequency responses.

The endoscopes met performance specifications in the following additional bench testing applied by IQ Endoscopes Ltd.
- Bending capability
- Rate of suction
- Working length
- Diameter of forceps channel
- Viewing direction

Clinical testing is not applicable for this submission.

The devices met pre-determined acceptance criteria against applicable aspects of consensus standards relating to Electrical Safety, Biocompatibility and Endoscope specific product standards that were applied in nonclinical testing, and also satisfied the required performances assigned by IQ Endoscopes during the additional bench testing performed.

The results from the non-clinical testing performed has verified that the devices are as safe and effective as the predicate with respect to their intended clinical use.