July 8, 2020

ConMed Corporation
Kavita Amin
Sr. Specialist, Regulatory Affairs
525 French Road
Utica, New York 13502

Re: K201593
Trade/Device Name: Looking Glass 4K Integrated Visualization System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 11, 2020
Received: June 12, 2020

Dear Kavita Amin:

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)*
K201593

Device Name
Looking Glass 4K Integrated Visualization System

Indications for Use *(Describe)*
The ConMed Looking Glass System is intended for use in a variety of endoscopic surgical procedures including but not limited to orthopedic, laparoscopic, urologic, sinuscopic, plastic and as an accessory for microscopic surgery.

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

Looking Glass™ 4K Integrated Visualization System

Submitter Name and Address:

ConMed Corporation
525 French Road
Utica, NY -13502
USA

Contact Person Name and Telephone:

Kavita Amin
Sr Specialist, Regulatory Affairs
Telephone: 508-948-2084

Date of Summary Prepared: June 11, 2020

Name of the device:

Trade Name: Looking Glass™ 4K Integrated Visualization System
Common Name: Looking Glass
Classification Name: Class II
Product Code**:** GCJ

Predicate Device:

The *Looking Glass™ 4K Integrated Visualization System* represents a change to the ConMed, *True HD 3MOS Camera System (IM8000).* The information presented in this submission demonstrates the *Looking Glass 4K Integrated Visualization System* is substantially equivalent in function and intended use as its predicate device, *True HD 3MOS Camera System*, and reference device, *4K UHD Monitor*. The list of predicate and reference devices are provided in **Table 1.**

Table 1: Predicate Device

	510(k) Number	**Product Code**	**Trade Name**	**Manufacturer**
Predicate Device	K161017	GCJ	True HD 3MOS Camera System	ConMed Corporation
Reference Device	510(k) Exempt	KQM	4K UHD Monitor, 32 in, 81 cm	Foreseeson Customs Displays, Inc.

Device Description:

The Looking Glass™ 4K Integrated Visualization System (Looking Glass System, LG4K) is a combined system that provides image visualization to the user during minimally invasive surgical procedures. The system is comprised of a 4K monitor with a built-in camera control electronics and the Camera Head. The Camera Head is connected to the Looking Glass via Cable Connector Interface (CCI).

The Camera Head is a hand-held, sterilizable portion of the system which gets connected to the CCI via electrical cable. The Looking Glass System is designed to be used with Standard Eye-Cup Endoscopes. Additionally, the system can be used in conjunction with other light sources, e.g. Xenon or LED. The Camera Head is offered in non-sterile configuration and requires sterilization prior to use via Autoclave Method.

Indications for Use:

The Looking Glass™ 4K Integrated Visualization System is intended for use in a variety of endoscopic surgical procedures, including but not limited to, orthopedic, laparoscopic, urologic, sinuscopic, plastic and as an accessory for microscopic surgery.

Summary of Technological Characteristics:

The modified device, *Looking Glass System*, uses the same technological characteristics as the predicate, *True HD 3MOS Camera System*, devices except for the following:

- The predicate device comprises of Camera Controller Unit (CCU) contained in a separate enclosure. The video output of the CCU is connected to a surgical monitor which displays a live video of the surgical field.
- Unlike the predicate device, the proposed device has camera control circuitry built-into surgical monitor
- The proposed camera head has 5 control buttons versus 2-button for predicate device. This modification is for the ease of surgeon to navigate the menu during procedure.

Therefore, based on this assessment, there are no significant technological differences between the two devices as described in the Substantial Equivalence section of this submission.

Performance Testing:

Performance Testing on the subject device was conducted to demonstrate that the device performs per its intended use and meets the specifications of the modifications as listed in the Substantial Equivalence Table. The tests results demonstrated the safety and effectiveness of the device is in accordance with design specifications and applicable standards.

- System Testing
  - Verification
  - Validation
- Standard Compliance
  - Electromagnetic compatibility, IEC 60601-1-2
  - Electrical Safety, IEC 60601-1
  - Safety and essential performance of endoscopic equipment, IEC 60601-2-18
- Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification test and their acceptance criteria were identified and performed as a result of this risk analysis assessment.
- The software verification and validation activities were performed in accordance with the IEC 62304.

Substantial Equivalence:

The subject device, *Looking Glass 4K Integrated Visualization System*, utilizes similar features and technological characteristics as the predicate device, *True HD 3MOS Camera System*. The only difference is the reconfiguration of the hardware and the use of the latest sensor technology. The modifications made to the camera head provides the surgeon options for navigation during a procedure.

Conclusion:

The modified device, *Looking Glass™ 4K Integrated Visualization System*, is substantially equivalent to the commercially available marketed device, *True HD 3MOS Camera System*. The modifications expressed in this 510(k) Premarket Notification are assessed using the performance data that are from well-established method and do not raise any new issues of safety and effectiveness.