DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 9, 2016

ConMed Corporation
Diair Cantisani
Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K161017
Trade/Device Name: True HD 3MOS Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 8, 2016
Received: April 12, 2016

Dear Diair Cantisani:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161017

Device Name

ConMed True HD 3MOS Camera System

Indications for Use *(Describe)*

The ConMed True HD 3MOS Camera 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
True HD 3MOS Camera System

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number K161017 as of March 31, 2016.

I. SUBMITTER

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

II. COMPANY CONTACT

Diair Cantisani,
Regulatory Affairs Specialist
Phone: 508-948-2084
Fax: 508-366-8858
Date Prepared: February 29, 2016

III. DEVICE

Device Trade Name:	True HD 3MOS Camera System
Common Name:	HD 3MOS Camera System
Classification Name:	Laparoscope, General & Plastic Surgery
Regulatory Class:	Class II, per 21 CFR 876.1500
Review Panel:	General and Plastic Surgery
Product Codes:	GCJ

IV. PREDICATE DEVICE

Device Name:	ConMed 3-CCD High Definition Digital Camera System
Company Name:	ConMed Corporation
510(k) #:	K063457

V. DEVICE DESCRIPTION

Modified Device

The ConMed True HD 3MOS Camera System consists of a camera control unit (CCU) and a camera head that is used in conjunction with endoscopes, light source, light guide cables, monitors and other ancillary equipment to allow for high definition visualization during minimally invasive surgical procedures.

Like the predicate device, sterilization of the camera head and cable is required before use. The camera heads must be sterilized using steam sterilization.

Unmodified Device

The ConMed HD Digital Camera System consists of a camera control unit (CCU) and a camera head that is used in conjunction with an endoscope to allow for high definition visualization during minimally invasive surgical procedures. Sterilization of the camera head and cable is required before use. The camera heads must be sterilized using steam sterilization.

VI. INTENDED USE / INDICATIONS FOR USE

The True HD 3MOS Camera 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.

VII. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

The ConMed True HD 3MOS Camera System has the same technological characteristics and design as the predicate device except for the following features:

- The camera head incorporates a CMOS image sensor in oppose to the CCD image sensor featured in the predicate device.
- The proposed device software system leverages key components from a camera base component procured from Panasonic (SOUP) versus the in-house developed software system utilized in the predicate device.
- Unlike the predicate device that outputs 1280 x 720 pixels and 1920 x 1080 pixels video resolution the proposed device True HD 3MOS Camera System outputs 1920 x 1080 pixels only.
- The camera control unit introduces a full metal chassis in oppose to the metal and plastic bezel chassis in the predicate device.

VIII. PERFORMANCE TESTING

Testing has been completed to demonstrate that the device performs as intended given the modification, and is substantially equivalent to the predicate device.

Completed test data includes the following:

- Performance testing were conducted to demonstrate that the True HD 3MOS Camera System performs according to specifications and functions as intended.

The tests results demonstrated the safety and effectiveness of the devices in accordance with design specifications and applicable standards.

- System Testing
  - Verification
    - Functional testing
    - Video Image
    - Software
  - Validation
    - Functional testing
    - Video Image
    - Software
- Standards evaluation
  - Electromagnetic compatibility, IEC60601-1-2
  - Electrical Safety, IEC60601-1
  - Particular Standard, safety and essential performance of endoscopic equipment, IEC60601-2-18
  - Reprocessing, AAMI TIR12
- Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.
- The software validation activities were performed in accordance with the IEC62304.
- The instructions for reprocessing of the camera heads of the subject devices include Cleaning and Sterilization. All cleaning and sterilization methods have been validated.

IX. SUBSTANCIAL EQUIVALENCE

The differences between the predicate devices and the proposed device do not raise any new risks of safety or efficacy. Supporting information in this submission confirms that the ConMed True HD 3MOS Camera System is safe and effective for its intended use and is substantially equivalent in design, intended use, principals of operation, and technical characteristics to the ConMed 3-CCD High Definition Digital Camera System (K063457).

X. CONCLUSION

Based upon the testing and analysis performed, the ConMed True HD 3MOS Camera System is as safe, as effective, and performs as well as the ConMed 3-CCD High Definition Digital Camera System (K063457) for image visualization and user interaction.