DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 30, 2015

Quest Medical Imaging
Mr. Martin Heuvelmans
Quality Assurance Manager
Industrieweg 41
1775 PW Middenmeer
Netherlands

Re: K143474
Trade/Device Name: Artemis Handheld Imaging System
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OWN, GCJ
Dated: May 18, 2015
Received: May 27, 2015

Dear Ms. Heuvelmans:

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" (21CFR 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 -S

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)*
K143474

Device Name
Artemis Hand Held Imaging System

Indications for Use *(Describe)*
The Artemis Handheld Imaging System is a fluorescent imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic, reconstructive and organ transplant surgeries.

The system uses direct visualization for open procedures, or via a laparoscope for minimally invasive procedures.

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.

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SECTION 6

510(k) Summary (21 CFR 807.92(c))

Administrative information

Manufacturer Name: Quest Medical Imaging
Industrieweg 41
1775 PW Middenmeer
Netherlands

Contact Person: Martin Heuvelmans, QA Manager
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FDA Establishment Registration Number: 3010590422

Date prepared: December 1st, 2014

Name of Device:

Trade Name:	Artemis Handheld Fluorescence Imaging System
Common Name:	Fluorescent Imaging System
Classification Name:	21 CFR 876.1500
Product Code:	OWN, GCJ

Identification of Predicate Device(s):

510(k) Number	Device	Manufacturer
K110480	PDE	Hamamatsu Photonics K.K. Hamamatsu City, Japan
K132475	Fluobeam 800 Clinic Imaging Device	Fluoptics, Grenoble Cedex, France

Intended Use Statement

The Artemis Handheld System is a fluorescent imaging system is used in capturing and viewing fluorescent images for the visual assessment of blood flow for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic, reconstructive and organ transplant surgeries.

The system uses direct visualization for open procedures, or via a laparoscope for minimally invasive procedures.

Device Description
The Artemis Handheld System is intended for intraoperative and minimal invasive visual assessment of blood vessels and related tissue perfusion, by enabling surgeons to observe fluorescent images of blood vessels and related tissue.

The Artemis System consists of a hand held camera, Artemis Fast Lens; ring light for open procedures, and a laparoscope for minimally invasive procedures, controller (lap top) and a light source or Light Engine. The Artemis Light Engine (K141164) is Class II device for illumination of surgical sites for diagnostic purposes. The light Engine has imaging capabilities for fluorescence as well. The laparoscope is an OEM item branded for Quest and cleared via 510(k) Number K945266.

Performance Testing
The performance testing to verify conformance to the original user / design requirements for both the system overall and the software was successfully conducted. Design Test and Verification demonstrates that the device functions as it is intended and its performance does not raise any issues of safety and effectiveness. Software is verification testing was successfully performed. The manufacturer complies with the following voluntary standards:

- IEC 60601-1-2 Edition 3: 2007-03 Medical Electrical Equipment Part1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements And Tests.
- ISO 14971 Second edition 2007-03-01, Medical Devices – Application of Risk Management to Medical Devices.

The Artemis Handheld Imaging System clinical evaluation included in vitro characterization, determining concentration dependent sensitivity of ICG dissolved in human serum albumin, and in in vivo animal models using nude Balb/c mice, as well as comparative imaging qualitative assessments with other NIR imaging devices on various anatomical structures. These studies also included human vital structure imaging performed at a medical research facility in the Netherlands. Further perfusion imaging was assessed in case series studies performed in Germany, satisfactorily demonstrating perfusion in the colon and in skin tissue after skin flap reconstruction.

Predicate Device Comparison
The Artemis System was compared to the PDE System, K 110480, and the Fluobeam 800, K132475. The systems have similar intended uses and employ the same mechanism of action of fluorescing a dye within the circulatory system. Minor differences are noted between the reference device and the predicates. The reference device does not raise any new questions of safety and effectiveness.

Conclusion
The Artemis System has similar intended use and technical features as the predicate devices listed above. Therefore, the Artemis System is substantially equivalent to the predicate marketed devices referenced herein.