February 19, 2020

ClearCam, LLC
% Ms. Prithul Bom, BA.MBA
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite # 510k
Saint Paul, Minnesota 55114

Re: K200228
Trade/Device Name: ClearCam System
Regulation Number: 21 CFR 876.1500
Regulation Name: Laparoscopes, General & Plastic Surgery
Regulatory Class: Class II
Product Code: GCJ
Dated: January 28, 2020
Received: January 30, 2020

Dear Ms. Prithul Bom:

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)*
K200228

Device Name
ClearCam System

Indications for Use *(Describe)*
The ClearCam System is indicated to provide lens clearing during laparoscopic 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. General Information

Submitter Name:	ClearCam Inc. Mr. Chris Idelson, PhD
Submitter Address:	1601 Trinity St., Bldg B M/S Z-1400 Austin, TX 78712
Submitter Telephone:	(410) 897-2858
Date Prepared:	October 9, 2019
Trade Names:	ClearCam System
Common Name:	Laparoscope, General & Plastic Surgery
Classification:	Class II per: 21 CFR 876.1500– Endoscope and accessories
Product Codes:	GCJ
Classification:	General & Plastic Surgery
Predicate Device(s):	Primary Predicate: ClickClean (K170103) Reference Device(s): EndoClear (K100346) Clearify (K062779)

2. Indications For Use/Intended Use

The ClearCam System is indicated to provide lens clearing during laparoscopic procedures.

3. Description Of The Device Subject To Premarket Notification:

The ClearCam System is a laparoscopic accessory lens clearing device consisting of a sheath and handle that slides over the laparoscope. The handle contains a wire connected to a wiper at the distal end of the sheath that provides lens clearing when activated. The device is intended to clear the intra-operative view of the surgical site during minimally invasive surgery by physically removing debris, blood, and bodily fluids from the laparoscope lens.

4. Technological Characteristics and Performance Specifications

The technological characteristics and performance specifications of the ClearCam System is similar to the primary predicate device cleared under K170103. The intended use is identical. The differences in the principal of operation have been extensively performance tested so as not to raise new questions of safety and effectiveness. Performance testing data follows.

5. PERFORMANCE DATA

Mechanical Testing

The mechanical function and structural integrity of devices were tested to demonstrate that the design specifications from design inputs are fulfilled listed in Table 1.

Table 1

Test Description	Method	Result
Sterilization	ISO 14937:2009 Sterilization of health care products	Pass
Performance - Mechanical	In accordance with device performance specifications	Pass
Performance - Functional	In accordance with device performance specifications	Pass
Performance - Pre-Clinical	Functional testing set by the standard ISO 8600-1:1997	Pass

Biocompatibility Testing

The biocompatibility evaluation and testing of the ClearCam System was conducted in accordance with the following standards and guidance, as recognized by the FDA Guidance - Use of International Standard ISO- 10993-1, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing within a risk management process", dated 06-16-2016 listed in Table 2.

Table 2

Test Description	Method	Result
Cytotoxicity	ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	Pass
Hemocompatibility	ISO 10993-4, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.	Pass
Sensitization	ISO 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Pass
Intracutaneous Reactivity	ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass
Systemic Toxicity (acute)	ISO 10993-11, Biological evaluation of medical devices- Part 11: Tests for systemic toxicity.	Pass
Pyrogenicity	ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Pass

6. SUBSTANTIAL EQUIVALENCE

As established in this submission, the ClearCam System was shown to be substantially equivalent and have equivalent technological characteristics to its primary predicate device based on consideration of the following characteristics listed in Table 3.

Table 3

Device Name / Device Attribute	Proposed Device ClearCam System (Subject Device)	Primary Predicate Device Laparoscope Lens Shield Device (LENS) - ClickClean (Legally Marketed: K170103)
Indications for Use	The ClearCam System is indicated to provide lens clearing during laparoscopic procedures.	Same
Where Used	Operating Room	Same
Prescription Only	Yes	Same
Target Patient	Patient under laparoscopic surgery	Same
Target User Population	Clinician who is qualified to perform a laparoscopic surgery	Same
Anatomical Site	Abdominopelvic cavity	Same
Method of Introduction	Introduced into abdominopelvic cavity via a trocar	Same
Biocompatibility	Externally communicating devices, in contact with tissue, with limited contact (≤ 24h) based on their intended use	Same
Product Code	GCJ	Same
Product Classification	Class II	Same
Material	Metal and Polyamide	Same
Diameter	5mm, 5.5mm, 10mm Laparoscope	Same
Sterility	Single Use, Ethylene Oxide Sterilization, SAL of 10-6	Same
Design Features / Components	Mechanical wiping of the distal lens to provide a clear view	Same

7. CONCLUSION

Based on the intended use, technological characteristics, comparison to the predicate device and performance testing, the ClearCam System is substantially equivalent to the predicate device and raises no different question of safety or effectiveness.