July 6, 2023

Guangdong OptoMedic Technologies, Inc.
Weijuan Guo
Regulatory Affairs Engineer
Suite 503, Building A, Golden Valley
Intellicreation Community, No. 2 Yonganbei Street
Foshan, 528200
China

Re: K231003
Trade/Device Name: Laparoscope (21033FA, 21033FC, 21033WA, 21033WC, 20533FA, 20533FC, 20533WA, 20533WC)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 9, 2023
Received: June 9, 2023

Dear Weijuan Guo:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.07.06 10:45:39 -04'00'

Mark Trumbore, 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: 06/30/2023
*See PRA Statement below.*

Submission Number *(if known)*

K231003

Device Name

Laparoscope (21033FA, 21033FC, 21033WA, 21033WC, 20533FA, 20533FC, 20533WA, 20533WC)

Indications for Use *(Describe)*

The OptoMedic Laparoscopes are intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs.
The OptoMedic Laparoscopes are intended to be used by trained healthcare professional in diagnostic and therapeutic 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.**

# 510(k) Summary

## Prepared in accordance with the requirements of 21 CFR Part 807.92

Date Prepared: March 31, 2023

### I. General Information

| | |
|---|---|
| 510(k) Submitter/Owner: | Guangdong OptoMedic Technologies, Inc.<br>Suite 503, Building A, Golden Valley Intellicreation Community, No. 2 Yonganbei Street, Daxu, Guicheng, Nanhai, Foshan, Guangdong, 528200, P.R. China<br>Establishment Registration Number: Not yet registered |
| Contact Person: | Jane Guo<br>Regulatory Affairs Engineer<br>Tel: +86 (757) 8670 2920<br>Email: guoweijuan@optomedic.com |

### II. Device Identification

| | |
|---|---|
| Device Trade Name: | Laparoscope |
| Common or Usual Name: | Laparoscope |
| Model: | 21033FA, 21033FC, 21033WA, 21033WC, 20533WA, 20533WC, 20533FA, 20533FC |
| Regulation Name: | Endoscopes and accessories |
| Regulation Number: | 21 CFR 876.1500 |
| Regulatory Class: | Class II |
| Product Code: | GCJ |

### III. Predicate Device

| | | |
|---|---|---|
| **Primary Predicate Device** | 510(k) Number: | K223923 |
| | Product Name: | HOPKINS Telescopes |
| **Secondary Predicate Device** | 510(k) Number: | K201151 |
| | Product Name: | O-Mec Laparoscopes 690 Series |

## IV. Device Description

The OptoMedic laparoscopes are rigid endoscopes that are used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. An endoscope is a slender, tubular optical instrument used as a viewing system for examining an inner part of the body. The inside of the endoscope contains a series of lenses that transmit the endoscopic image, which is illuminated by an external light source.

The Laparoscope has 8 models which are available in two insertion portion widths (5.6 mm and 10.1mm), two working lengths (320mm and 310mm) and two different directions of view (0° and 30°). The specifications of the proposed laparoscopes are listed in Table 1.

Table 1 Model Specifications

| No. | Model | Direction of View | Maximum Insertion Portion Width | Working Length |
|---|---|---|---|---|
| 1 | 21033FA | 0° | 10.1mm | 330mm |
| 2 | 21033FC | 30° | 10.1mm | 330mm |
| 3 | 21033WA | 0° | 10.1mm | 330mm |
| 4 | 21033WC | 30° | 10.1mm | 330mm |
| 5 | 20533FA | 0° | 5.6mm | 310mm |
| 6 | 20533FC | 30° | 5.6mm | 310mm |
| 7 | 20533WA | 0° | 5.6mm | 310mm |
| 8 | 20533WC | 30° | 5.6mm | 310mm |

## V. Indications for Use

The OptoMedic Laparoscopes are intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs.
The OptoMedic Laparoscopes are intended to be used by trained healthcare professional in diagnostic and therapeutic procedures.

## VI. Comparison of Technological Characteristics with The Predicate Device

Table 2 General Comparison

| **Description** | **Subject Device (K231003)** | **Primary Predicate Device (K223923)** | **Secondary Predicate Device (K201151)** |
|---|---|---|---|
| Regulation Number | 21 CFR 876.1500 | 21 CFR 876.1500 | 21 CFR 876.1500 |
| Product Code | GCJ, HET, NMH | GCJ | GCJ |
| Device class | Class II | Class II | Class II |
| Indication for use | The OptoMedic Laparoscopes are intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. The OptoMedic Laparoscopes are intended to be used by trained healthcare professional in diagnostic and therapeutic procedures. | For telescopes with diameter ranging from 3mm-5mm： The HOPKINS Telescopes are intended to provide visualization during laparoscopy, thoracoscopy and general surgery in adults and pediatrics. For telescopes with diameter ranging from 5.5mm- 11mm： The HOPKINS Telescopes are intended to provide visualization during laparoscopy, thoracoscopy and general surgery in adults. | The O-Mec Laparoscopes 690 Series (Models, 90-331000H, 690-331030H, 690-300500H, 690-300530H) are intended to be used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments. |
| Prescription/ Over-the-counter use | Prescription | Prescription | Prescription |
| Single use /Reusable | Reusable | Reusable | Reusable |
| Principle of operation | The illumination light enters the laparoscope from the light guide cable, and exits from objective lens to irradiate the tissue. The light reflected by the tissue is collected and transmitted by the laparoscope compatible with a camera head. The image information is converted into an image signal through the camera head and finally displayed on the monitor. | The HOPKINS Telescopes are rigid telescopes that utilize the rod lens technology. At the distal end of the telescope's shaft is the lens and the other end of the shaft is attached to the eyepiece. Throughout the central lumen of the HOPKINS Telescopes, optical glass rods are used to transmit and magnify the image received from | The illumination light enters the laparoscope from the light guide cable, and exits from objective lens to irradiate the tissue. The light reflected by the tissue is collected and transmitted by the laparoscope compatible with a camera head. The image information is converted into an image signal through the camera head and finally displayed on the |

| | | | |
|---|---|---|---|
| | | the lens. | monitor. |
| **Physical Characteristics** | | | |
| Endoscope Type | Rigid endoscope | Rigid endoscope | Rigid endoscope |
| Working Length | 310mm, 330mm | 18cm- 50cm | 331mm, 334mm, 301mm, 303mm |
| Maximum insertion portion width | 5.6mm, 10.1mm | 3mm- 11mm | 10.1mm, 5.5mm |
| **Optical Characteristics** | | | |
| Direction of View | 0°, 30° | 0°, 6°, 30°, 45° | 0°, 30° |
| Field of View | 68°, 75° | 55°- 80° | 75° |
| Light source | External | External | External |
| **Reprocessing Methods** | | | |
| Cleaning | Manual, Automatic | Manual, Automatic | Manual |
| Sterilization | Steam sterilization /Low temperature plasma sterilization | Steam (prevacuum), STERRAD 100S, STERRAD NX, STERRAD 100NX, STERIS VPRO1, VPRO 1 Plus | Autoclavable |

The differences technological characteristics do not raise different questions of safety and effectiveness.

**VII. Performance data**

Non clinical tests were conducted to verify that the proposed device met all design specifications as is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ANSI/AAMI ES 60601-1: 2005+A2 (R2012) +A1 Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 8600-1-2015 General requirements
- ISO 8600-3-2019 Determination of field of view and direction of view of endoscopes with optics
- ISO 8600-4-2014 Determination of maximum width of insertion portion
- ISO 8600-5-2020 Determination of optical resolution of rigid endoscopes with optics
- 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 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-23:2021Biological evaluation of medical devices - Part 23: Tests for irritation

- AAMI TIR 30:2016 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- AAMI TIR 12:2020 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

Performance testing were also conducted on the subject device and demonstrate that the proposed system performs according to specifications and functions as intended.

**VIII. Conclusions**

The performance testing summarized above supports a substantial equivalence determination. The performance testing demonstrate that the subject device is as safe and as effective as the legally marketed predicate device.