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

February 4, 2015

Stryker Endoscopy
% Mr. Dave Yungvirt
Third Party Review Group, LLC
45 Rockafeller Plaza
New York, New York 10111

Re: K150127
Trade/Device Name: Laparscopic Handles with PEEK Insulation
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 19, 2015
Received: January 20, 2015

Dear Mr. Yungvirt:

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
-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)*
K150127

Device Name
Laparoscopic Handles with PEEK Insulation

Indications for Use *(Describe)*
The Laparoscopic Handles with PEEK Insulation are indicated for use in endoscopic surgical procedures through cannulae to perform cutting, dissecting, retracting, and manipulating functions.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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."

I. SUBMITTER

Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138

Phone: 408-855-6377
Fax: 408-754-2969

Contact Person: Rebecca Goldberg
Date Prepared: January 16, 2015

II. DEVICE

Name of Device: Laparoscopic Handles with PEEK Insulation
Common or Usual Name: Endoscopic Forceps/Graspers/Scissors
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: II
Product Code: GCJ

III. PREDICATE DEVICE

K&W 2-Piece Take-Apart Instruments, K973259

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Laparoscopic surgical manual instruments (containing a Laparoscopic Handle with PEEK Insulation and manual instrument insert) are intended for cutting, holding, grasping and manipulation of tissue, organs, organ areas, and surgical auxiliaries such as suturing material. Some instruments have radiofrequency (RF) ports which allow them to be used for electrosurgery. The Laparoscopic Handles with PEEK Insulation (herein referred to as 'proposed device') can be used in combination with the predicate 5 mm inserts cleared in K973259. The proposed devices are designed to be sterilized by the end user using either the US or EU standard pre-vacuum sterilization cycles.

V. INDICATIONS FOR USE

The Laparoscopic Handles with PEEK Insulation are indicated for use in endoscopic surgical procedures through cannulae to perform cutting, dissecting, retracting, and manipulating functions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Manipulation and cutting of tissue using mechanical or electrosurgical means is the technological principle for both the proposed and predicate devices. These functions are based on using surgical tools to access internal tissues and organs within the abdominal cavity.

The following differences exist between the proposed and predicate devices:

- Use of different shaft insulation material
- Use of different glue between the shaft and shaft insulation

VII. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility Testing:

The biocompatibility evaluation and testing of the Laparoscopic Handles with PEEK Insulation was conducted in accordance with the following as recognized by the FDA:

- FDA Blue Book Memorandum #G95-1 "Use of International Standard 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" May 1, 1995,
- ISO 10993-1:2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,"
- ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
- ISO 10993-11, Biological evaluation of medical devices- Part 11: Tests for systemic toxicity.

The Laparoscopic Handles with PEEK Insulation are considered External Communicating Devices: Tissue/Bone/Dentin with limited contact duration (<24 hours). Cytotoxicity, Intracutaneous Reactivity, Sensitization and Acute Systemic Toxicity testing was performed on the finished devices which had undergone simulated use and reprocessing per the Instructions for Use. All biocompatibility testing had passing results.

Sterilization Validation:

The Laparoscopic Handles with PEEK Insulation are provided to user non-sterile and must be sterilized prior to the initial and each subsequent use. Sterilization validation was conducted in accordance with ISO 17665-1:2006 "Sterilization of Health Care Products Moist Heat Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices". Sterilization has been validated to ensure a Sterility Assurance Level of 10^{-6}.

Electrical Safety:

Electrical safety testing was conducted on the Laparoscopic Handles with PEEK Insulation. The proposed devices comply with the ANSI/AAMI ES60601-1:2005 + A2 (R2012) +A1 "Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance" standard for safety and the IEC 60601-2-2:2009 "Medical Electrical Equipment – Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories" for high frequency devices.

Mechanical Testing:

- Shaft deflection
- Monopolar cycling (Reliability of electrical insulation through repeated firing of monopolar energy)

VIII. CONCLUSIONS

The submitted information in this premarket notification is complete, and based on the indications for use, technological characteristics, performance testing and comparison to the predicate devices, the Laparoscopic Handles with PEEK Insulation raise no new questions of safety or effectiveness and can be considered to be substantially equivalent to the predicate devices.