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

October 7, 2016

Gyrus Acmi, Inc.
Graham Baillie
Regulatory Affairs Manager
136 Turnpike Rd
Southborough, Massachusetts 02649

Re: K161038
Trade/Device Name: PK Morcellator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, HET
Dated: September 21, 2016
Received: September 26, 2016

Dear Graham Baillie:

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,

For Division

Douglas Silverstein -S
2016.10.07 07:44:30 -04'00'

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K161038

Device Name
PK Morcellator

Indications for Use *(Describe)*

PK Morcellator WA90200A
The PK Morcellator is intended for cutting, and extracting tissue in laparoscopic gynecologic procedures.
It is recommended to use the PK Morcellator in conjunction with the PneumoLiner containment device (WA90500US) for removal of uterine tissue.

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.

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# 510(k) Summary
# K161038
# Olympus PK Morcellator

## General Information

| | |
|---|---|
| Manufacturer: | Gyrus Medical Ltd.<br>Fortran Road, St. Mellons<br>Cardiff, United Kingdom CF3 0LT |
| Establishment Registration Number: | 9617070 |
| 510(k) Submitter: | Gyrus ACMI, Inc.<br>136 Turnpike Rd.<br>Southborough, MA 01772-2104 |
| Establishment Registration Number: | 3003790304 |
| Contact Person: | Graham A. L. Baillie<br>Regulatory Affairs Manager |
| Date Prepared: | Oct 6, 2016 |

## Device Identification

| | |
|---|---|
| Classification Name: | Laparoscope, Gynecologic and accessories (21 CFR 884.1720), Class II, Obstetrics/Gynecology Panel;<br>Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400), Class II General and Plastic Surgery Panel |
| Procode(s): | GEI: Electrosurgical, Cutting & Coagulation & Accessories<br>HET: Laparoscope, Gynecologic (And Accessories) |
| Trade Name: | PK Morcellator |
| Generic/Common Name: | Laparoscopic Power Morcellator |
| Device name / Model Number | PK Morcellator / WA90200A |

## Predicate Device

| | |
|---|---|
| Gyrus ACMI PKS Plasma Morcellator | K080093<br>No recalls reported for predicate device |

## Device Description

The proposed PK Morcellator is configured in an ergonomically friendly pistol grip configuration, and includes an axially oriented hollow shaft. The pistol grip integrates the electrical connection cable that allows bipolar RF energy to be supplied by the electrosurgical generator to the tissue site located at the distal end of the hollow shaft. The design of the pistol grip body is such that a clinician may utilize a "ski-pole" grip on the Morcellator body, if that is their preference. The proposed PK Morcellator incorporates an improved smoke evacuation system to provide improved visibility during procedures. Smoke management can alternate between intermittent or constant by activating a trigger lock on the handle.

The hollow shaft of the Morcellator has an operative length of approximately 15 cm, extending distally from the pistol grip body. The surface of the Morcellator shaft is smooth, allowing the device to be introduced to the operative site through a trocar cannula seal, or with the use of the optional obturator, through an abdominal port. To facilitate optimal placement of the device during laparoscopic procedures, a depth stop normally located at the distal end of the pistol grip (at the junction of the pistol grip and Morcellator shaft), may be moved distally along the Morcellator shaft. The shaft has a nominal outer diameter of 15 mm, and a nominal inner diameter of 12 mm. The proximal end of the shaft also includes an elastomeric reducer that permits the passage of a grasper to the operative site and removal of tissue from the operative site, while preventing loss of pnuemoperitoneum.

## Intended Use

"PK Morcellator WA90200A
The PK Morcellator is intended for cutting, and extracting tissue in laparoscopic gynecologic procedures. It is recommended to use the PK Morcellator in conjunction with the PneumoLiner containment device (WA90500US) for removal of uterine tissue."

Comparison with predicate intended use:

The predicate PKS Morcellator (K080093) was cleared with the following intended use statement:

"The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures."

Differences between the proposed and predicate statements:

- The name has been modified from Gyrus ACMI PKS Plasma Morcellator to PK Morcellator.
- Coring has been deleted from the proposed K161038 intended for use statement.

Comment: The proposed PK Morcellator has a lip on the distal tip that allows a "peeling" removal of tissue as compared to the predicate "coring" technique.

- Laparoscopic general surgical procedures and laparoscopic urological procedures have been deleted from the proposed intended use.

  Comment: The bovine tongue tissue model evaluated in this submission is a more appropriate model for laparoscopic gynecological indications.

- The proposed statement now recommends the use the PK Morcellator in conjunction with the PneumoLiner containment device (WA90500US) for removal of uterine tissue

  Comment: Validation testing confirmed the compatibility, safety and efficacy of the PK Morcellator when used with the ASC Pneumoliner for the removal of uterine tissue.

The aforementioned differences between the predicate and proposed indications do not affect the safety and effectiveness of the device and do not alter the intended surgical use of the device.

## Comparison of Technological Characteristics

The proposed PK Morcellator utilizes bipolar electrosurgical energy to cut tissue which is the same as the predicate PKS Plasma Morcellator. In addition the proposed PK Morcellator is dimensionally similar to the PKS Plasma Morcellator, having similar Morcellator shaft diameters. Like the predicate device the proposed PK Morcellator utilizes a pistol grip Morcellator with a hollow shaft through which a grasper is passed to grasp tissue to be resected. The proposed and predicate morcellators are sterilized for single use only.

The subject and predicate devices have similar technology, principles of operation, performance, dimensions and materials. A side-by-side comparison of the marketed and proposed devices is provided below.

| Feature | Predicate K080093 | Proposed |
|---|---|---|
| Working Length | 15 cm | 15 cm |
| Shaft ID/OD | 12 mm / 15mm | 12 mm / 15 mm |
| Distal tip OD | 15 mm | 15 mm |
| Mode of tissue dissection | Bipolar RF energy | Bipolar RF energy |
| Morcellation technique | "Coring" morcellation technique yields round slugs of tissue removal | A lip added to distal cutting tip promotes a more efficient "Peeling" method of tissue morcellation |
| Generator Compatibility | Gyrus PK SuperPulse; and Gyrus General Surgery Workstation | Olympus ESG-400 |
| Power Input | 300W max., 200W nominal | 300W max., 200W nominal |
| Sterilization | $10^{-6}$ SAL, by Ethylene Oxide | $10^{-6}$ SAL, by Ethylene Oxide |
| Electrical Safety | Meets IEC 60601-1, IEC60601-2-2 | Meets IEC 60601-1, IEC60601-2-2 |

| Feature | Predicate K080093 | Proposed |
|---|---|---|
| Grasper Shaft/Jaw | Anodized Aluminum/SS 303 | N/A No Graspers included |
| Smoke Evacuation | Passive | Active |

## Summary of Non-Clinical Testing

Biocompatibility testing on all patient contacting surfaces has been performed in compliance to relevant requirements of ISO-10993. Biocompatibility testing included the following tests:

- ISO 10993-5, 2009 Biological evaluation of medical devices – Part5: Tests for in vitro cytotoxicity
- ISO 10993-10, 2010 Biological evaluation of medical devices. Tests for irritation and sensitization
- ISO 10993-11:2006. Biological evaluation of medical devices. Tests for systemic toxicity

The Olympus PK Morcellator will be delivered in a sterile state and is intended for single patient use only. Sterilization (ethylene oxide) and packaging of the device was validated using the following standards:

- ANSI/AAMI/ISO 11607-1, 2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ANSI/AAMI/ISO 11135-1, 2007 Sterilization of health-care products – ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

Packaging integrity and performance testing on devices that had undergone accelerated aging support a labeled three year shelf life.

Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the PK Morcellator. The device complies with the following standards:

- AAMI/ANSI ES60601-1:2005/(R)2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment – Part1: General Requirements for basic safety and essential performance
- IEC 60601-2-2: 2009 Medical electrical equipment. Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Bench Testing

Bovine tongue was selected as the tissue model for the PK Morcellator representing normal uterine tissue along with porcine/bovine blood to provide comparable eschar

build up and ingress at the tip of the device as would occur during a procedure. The following non-clinical/bench performance tests were conducted without the containment device:

| Test Ref | Description | Objective |
|---|---|---|
| **VE28** | **Device HF Dielectric Strength Test** | Device to withstand specified peak voltage for 30 secs when wrapped in a saline soaked cloth. No breakdown of the insulation shall occur |
| **VE20** | **Device Mains Dielectric Test** | Device to withstand specified voltage when wrapped in a saline soaked cloth for 30 secs. No breakdown of the insulation or flash over. |
| **VE31** | **System Compatibility** | Accurate default setting |
| **VE54** | **Cable Surface Temperature Test** | Over the duration of the procedure the temperature of the cable shall not exceed specified temp for more than 1 minute. |
| **VE22** | **Device Through Cannula** | Withstands insertion into 15mm cannula (3 times) |
| **VE10** | **Enteral Adaptor Strength Test** | Device withstands assembly with tubing |
| **VE13** | **Force to Depress Trigger – Before Conditioning** | Force to depress trigger must be between specified limits |
| **VE29** | **Suction, Flow Rate and Leakage – Before Conditioning** | Flow rate between specified volume rate with a specified suction pressure when trigger depressed using Olympus KV5 Suction unit |
| | | Device must provide Constant suction |
| | | Loss of insufflant less than 1 L/min with -700 mm/Hg suction pressure when trigger not activated and using the Olympus KV-5 suction unit |
| **VE34** | **Trigger Assembly Endurance** | Trigger must function after application of specified force for 225 cycles |
| **VE13** | **Force to Depress Trigger – After Conditioning** | Force to depress trigger must be between specified limits. |
| **VE52** | **Distal Tip Seal Test** | No leak path permissible between outer shaft and overmold active ring at 50 mm/Hg |
| **VE19** | **Obturation (Normal use)** | No damage to device after application of specified Torsional force , during inspection. |
| | | No damage to device after application of specified force applied to obturator during normal use. |
| **VE26** | **Seal Durability** | Leakage through shaft valve less than specified rate when no instrument inserted and no significant damage (tear or section removed >3mm) on inspection |
| | | Leakage through shaft seal less than specified rate at the end of the procedure. Using Storz 1x1 grasper for 50% of testing and the Olympus 3x2 for 50% |
| | | Loss of insufflant less than specified volume when obturator is fully inserted |
| | | Loss to be less than specified volume over 10 insertions and retractions of the grasper after completing morcellation. |

| Test Ref | Description | Objective |
|---|---|---|
| | | Loss of insufflation less than specified rate upon completion of morcellation |
| | | After completing morcellation with a 10mm instrument, leakage through shaft valve to be less than specified volume when no instrument inserted and no significant damage (tear or section removed >3mm) on inspection |
| | | Valve and Shaft seals intact after morcellating tissue |
| | | Valve and Shaft seals intact after insertion/retraction of 5mm adaptor (for specified cycles) |
| **VE09** | **Depth Stop Removal** | Tip remains intact and functional after removal and after completing morcellation |
| **VE14** | **Force to Insert 5mm Adaptor** | Force to insert meets specified acceptance criteria |
| **VE16** | **Force to Remove 5mm Adaptor** | Force to remove adaptor to be meet specified acceptance criteria upon completion of morcellation. |
| **VE15** | **Force to Lock/Unlock Trigger** | Force to unlock between specified limits. |
| **VE21** | **Tip Push Out Force** | No damage to device after obturation. |
| | | Device withstands specified force at the tip, after completing morcellation. |
| **VE37** | **Cantilever Force Test** | Intact and functioning after application of specified weight. |
| | | Meets force specification after completing morcellation. Tip to be positioned so that resultant torque force is applied to beak at 90°. |
| **VE33** | **Tip Force Test** | Tip withstands specified force when removing depth gauge, after completing morcellation. |
| | | Tip withstands specified force when removing depth gauge, after completing morcellation. |
| | | > than specified force after completing morcellation. |
| **VE27** | **Shaft Force Test** | Shaft withstands specified force when removing Depth Stop, after completing morcellation. |
| | | Device withstands >44.1 Ncm when removing depth gauge, after completing morcellation. |
| | | Tip remains functional and intact after completing morcellation |
| | | Meets specification after completing morcellation. |
| **VE49** | **Part B Drop Test** | No unacceptable risk after drop test. No damaged or loose parts that could lead to user or patient harm |
| **VE49** | **Part C – Mold Stress Relief** | No unacceptable risk after being heated to specified temp for 7 hours. No damaged or loose parts that could lead to user or patient harm. |
| **574414 ID 140.02** | **Blister Peel Strength** | Blister peel seal strength meets specification |
| **VE05** | **Cable Insulation Mains Dielectric Strength Test** | Cable to withstand specified voltage when immersed in a bath of saline for 5 mins. No breakdown of the insulation shall occur |
| **VE04** | **Cable Insulation HF** | Cable HF leakage shall not exceed the specified limit |

| Test Ref | Description | Objective |
|---|---|---|
| | **Leakage Test** | when wrapped in a saline soaked cloth and tested at specified Vpeak |
| **VE03** | **Cable Insulation HF Dielectric Strength Test** | Cable to withstand specified peak voltage for 30 secs after pre-conditioning in saline. A bare conductive wire wrapped a maximum of 5 turns around the cable. No breakdown of the insulation shall occur. |
| **VE06** | **Continuity** | Active & Return resistance between tip and plug pins, out of the box. |
| **VE17** | **Force to Remove Obturator** | Force to remove obturator meets specification |
| **VE07** | **Cutting Force** | Maintains specified force for the duration of the procedure. Using the same grasper for back-to-back testing |
| | | Pull force equivalent or less than SORD I + G400 for the duration of the procedure using the same grasper for back-to-back testing |
| **VE08** | **Cutting Speed** | Cutting speed equivalent or greater than SORD I + G400 for the duration of the procedure using the same grasper for back-to back testing |
| **VE35** | **Trigger Lock Force Test** | Trigger lock must be able to withstand application of specified force |
| **VE36** | **Trigger Lock Function (Trigger Released)** | No adverse effects by locking without depressing trigger |
| | | Trigger lock must remain functioning after specified cycle |
| **VE46** | **Cable Anchorage** | The cord shall not have worked loose or show any damage, including a short circuit, after oscillating for specified cycles and cycle rate |
| **VE32** | **Tip Durability (Conditioning)** | Workstation must provide foot switching capability |
| | | Device is activated by footswitch |
| | | Compressive force after completing morcellation meets specification |
| | | Maximum stall out force meets specification |
| | | Device tip successfully completes blanch test after 5 seconds |
| | | Only activates at active tip for the duration of the procedure |
| | | Device remains functional (initial tissue mass of 1.425Kg) |
| | | Device remains intact and functioning after application of specified impact force, throughout morcellation. Using Jarit 1x1 grasper |
| | | Device driven by workstation |
| **VE48** | **Shaft Temperature Test** | Over the duration of the procedure the temperature of the device shall not exceed specified temperatures at various time intervals. |
| **VE51** | **IPA Wipe Test on Shaft Insertion Depth Markings** | Remain clearly legible on completion of wipe test with the following media; Methylated Spirits, Distilled Water, IPA |

| Test Ref | Description | Objective |
|---|---|---|
| **VE29** | **Suction, Flow Rate and Leakage Test -After Conditioning** | The minimum flow rate at the end of the procedure (after morcellating tissue of initial mass ) to be equal to or greater than specified limit |
| | | Loss of insufflant less than specified volume with -700 mm/Hg suction pressure when trigger not activated and using Olympus KV-5 suction unit<br>Constant suction |
| **VE32** | **Tip Durability Part B – Silicone Erosion** | Silicone rubber erosion rate evaluated to be at maximum specified rate<br>Detached fragments of silicone are not acceptable. |
| **VE25** | **5mm Adaptor Retention** | 5mm adaptor retained when Gyrus ACMI 5.5mm scope inserted and removed |
| **VE24** | **5mm Adaptor Endurance** | Withstands specified insertion and removal cycles, after completing morcellation |
| **VE02** | **Tip Grasper Force Test** | Withstands specified rotational force after completing morcellation |
| | | Intact and functioning after application of > 60N impact, throughout morcellation. |
| | | Withstands specified rotational force after completing morcellation |
| **VE49** | **IEC60601 Mechanical Testing Part A – Push Test** | No unacceptable risk after push test. No damaged or loose parts that could lead to user or patient harm |
| **VE23** | **Obturation (Forseeable Misuse)** | Torsional force, during insertion meets specification |
| | | Force applied to the handle during foreseeable misuse. |
| **VE30** | **Force to Remove Filter Assembly** | No damage to device after application of specified force after completing morcellation |
| **920315** | **Dye Penetrant Test** | Dye ingress permissible providing ≥7.5mm of 'adhesive transfer seal width' remains intact. |

Human Factors/Usability Engineering

Inputs to the PK Morcellator requirements have included user feedback from PKS PlasmaSORD, which has been in clinical use for over 5 years. The PK Morcellator is an upgrade of the PKS PlasmaSORD to include an integral smoke extraction system to improve visibility, and a beak to promote tissue peeling, and avoid coring.

The subject of usability has been widely considered during the four year development of the PK Morcellator, with the opinions of users regularly sought and fed back into the instrument design. Usability evaluation included surgeons with varying levels of experience and utilized various bench models and an animal model for assessments. The instructions for use were validated to ensure they provide clear and concise statements which convey to the user the correct modes of use, an understanding of the functionality offered, the nature of the tissue effect obtained and how to avoid potential hazards. In summary, the verification and validation activities successfully demonstrated that the usability characteristics of the user interface have met the acceptance criteria.

Containment System Compatibility

During the development of the PK Morcellator, evaluations were conducted to demonstrate the successful deployment of the PK Morcellator in a containment system. The purpose of the compatibility validation was to ascertain that the PK Morcellator device can function as expected in conjunction with the containment system chosen for validation. Test criteria evaluated the insertion/removal of the device, as well as morcellation within the containment system. The overall conclusion, as regards compatibility of the validation of the PK Morcellator device when used in conjunction with the ASC PneumoLiner containment system is that the function of the morcellator remained unaffected.

Additionally, Advanced Surgical Concept (ASC) performed an evaluation to show compatibility of the PneumoLiner Containment Device, with different morcellators, including the PK Morcellator. The purpose of ASC's design validation was to show that the PneumoLiner device can be used safely and effectively by users. Testing in bench models simulating clinical use and a porcine model by trained laparoscopists with a range of experience, demonstrate that the PK Morcellator can be used within the PneumoLiner without any adverse effects on the design or performance of either device. The overall conclusion of was that "the PneumoLiner" device meets user needs and has been shown to be able to be used safely and effectively by users using all of the tested morcellators, including the PK Morcellator.

**Conclusion:**

Performance testing summarized above demonstrates that the proposed PK Morcellator is substantially equivalent to the predicate device and that the PK Morcellator can be used in conjunction with the PneumoLiner containment device.