



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

December 23, 2015

Endoplus  
% E.J. Smith  
Consultant  
Smith Associates  
1468 Harwell Avenue  
Crofton, Maryland 21114

Re: K151567

Trade/Device Name: Endoplus Hand-held Laparoscopic Instruments  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: June 8, 2015  
Received: June 10, 2015

Dear E.J. Smith:

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,

**Binita S. Ashar -S**

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

**Indications for Use**

510(k) Number (if known)

K151567

Device Name

Endopus Hand Held Laparoscopic Instruments

Indications for Use (Describe)

Endopus Hand held Laparoscopic instruments are intended for grasping, cutting, dissecting, retracting, clamping, biopsy, and/or cauterization of tissue. The devices are used in conjunction with a laparoscope during laparoscopic procedures. Instruments should be used only by personnel completely familiar with their operation. Using an instrument improperly for a task which it was not intended may result in a damaged or broken instrument.

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)

## 510(k) Summary

### SPONSOR

Company Name: ENDOPLUS

Company Address: 750 Tower Road, Suite A  
Mundelein, IL 60060

Telephone: 800.236.5972

Contact Person: Matthew Gudeman

Summary Preparation Date: December 23, 2015

### DEVICE NAME

Trade Name: ENDOPLUS Hand held Laparoscopic  
Instruments Common/Usual Name: Hand-held Surgical Instruments

Classification Name: Electrosurgical, cutting & coagulation &  
accessories

Regulation Number: 21 CFR 878.4400

Product Code: GEI

Device Class: Class II

### PREDICATE DEVICE

Legally Marketed Equivalent Device

| Manufacturer                   | Brand Name  | 510(k) Number |
|--------------------------------|---|---------------|
| Pajunk GmbH Medizintechnologie | Pajunks disposable inserts for<br>handled instrument and HF<br>Electrodes | K062072       |

### DEVICE DESCRIPTION

The devices are commonly named hand held laparoscopic instruments. Specifically, each instrument has a different tip or jaw to define the functional use, such as scissors, forceps, graspers, biopsy, dissectors or needle holders. The devices are designed to be used through a portal, the opening maintained by an introducer or cannula which allows for insertion and removal of the device without damage to surrounding soft tissue. The devices have a linkage mechanism connecting the working tips, or jaws to a handle. This allows the surgeon to cut, dissect, grasp, clamp, cauterize, palpate, or retract at the operating site in conjunction with a laparoscope.

**DEVICE INDICATIONS FOR USE**

Hand held Laparoscopic instruments are intended for grasping, cutting, dissecting, retracting, clamping, biopsy, and/or cauterization of tissue. The devices are used in conjunction with a laparoscope during laparoscopic procedures. Instruments should be used only by personnel completely familiar with their operation.

**SUBSTANTIALLY EQUIVALENCE COMPARISON TABLE**

| Parameters           | Endoplus  | Pajunk GmbH   | Comments  |
|----------------------|---|---|-----------|
| 510(k) Number        |   | K062072   |           |
| Indications for Use  | Endoplus Hand held Laparoscopic instruments are intended for grasping, cutting, dissecting, retracting, clamping, biopsy, and/or cauterization of tissue. The devices are used in conjunction with a laparoscope during laparoscopic procedures. Instruments should be used only by personnel completely familiar with their operation. Using an instrument improperly for a task which it was not intended may result in a damaged or broken instrument. | <b>Pajunks</b> disposable inserts are instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures. | Similar   |
| User Environment     | For use by physician in the operating room  | For use by physician in the operating room  | Identical |
| Monopolar            | Yes   | Yes   | Identical |
| Length               | 20cm to 50cm  | 33cm to 45cm  | Similar   |
| Minimum Cannula Size | 5.5cm   | 5.5cm   | Identical |
| Handle Design        | Pistol Grip   | Pistol Grip   | Identical |
| Shaft Rotation       | Yes   | Yes   | Identical |
| Shaft Flexibility    | Rigid   | Rigid   | Identical |

| Parameters                | Endoplus  | Pajunk GmbH   | Comments  |
|---------------------------|---|---|-----------|
| Shaft Diameter            | 5mm   | 5mm   | Identical |
| Articulating Component    | Does not articulate   | Does not articulate   | Identical |
| Actuation Mechanism       | Handle Operation causes opening and closing of end effector | Handle Operation causes opening and closing of end effector | Identical |
| Flush Port                | Yes   | No  | Different |
| Insertion through trocar  | Yes   | Yes   | Identical |
| Form inserted into trocar | Jaws closed   | Jaws closed   | Identical |
| Reusable/Disposable       | Reusable Handle, Shaft and Insert                           | Disposable Insert Reusable Handle and Shaft Assembly        | Different |

## DIFFERENCES

- Endoplus includes a flush port feature for introducing cleaning fluids during the cleaning and providing a means for steam to enter during the sterilization process.
- Endoplus's inserts are reusable and Pajunk's inserts are disposable.

## COMPARISON OF TECHNICAL CHARACTERISTICS

The Endoplus Hand held Laparoscopic instruments has a similar Indications for Use and identical technological characteristics to the predicate device. Any material differences were addressed by biocompatibility, performance and electrical testing found below:

## PERFORMANCE DATA

### Safety Testing

### Electrical and EMC Testing

Endoplus performed the following electrical tests:

- IEC 60601-1: 2012 3<sup>rd</sup> edition - Medical electrical equipment—Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.

- 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

### **Cleaning and Sterilization**

The Reusable Hand-held Laparoscopic instruments are evaluated based on the following tests:

- Manual cleaning validation study and Laparoscopic Instrument Rack TOC analysis (AAMI TIR30:2011)
- Manual cleaning validation study and Laparoscopic Instrument Rack Protein analysis
- Steam Pre-vacuum Efficacy Validation Study
- Steam Sterilization Validation Study
- Shelf Life Protocol

### **Biocompatibility**

In accordance with ISO 10993-1, Hand-held Laparoscopic instruments are categorized as externally communicating devices in contact with circulating blood for less than 24 hours. The following tests are recommended by ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Intracutaneous
- Hemolysis

### **Performance Testing:**

- PLTW Comparative Ex-Vivo Thermal Tissue Testing Validation Study
- Electrical Safety Validation Report (Electrical Safety Testing)
- Scissors Performance Testing
- Expected Life Testing

### **CONCLUSION**

The Endoplus Hand held Laparoscopic instruments has a similar Indications for Use and identical technological characteristics to the predicate device. Biocompatibility and

performance testing has been performed to verify safe use and effective use. Endoplus concludes that Endoplus Hand held Laparoscopic instruments are substantially equivalent to the predicate device and introduces no new issues of safety and effectiveness.

Below is a complete listing of laparoscopic instruments covered by this 510(k) submission:

| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>                          |
|-------------------------|----------------------|-------------|---------------|--|
| 5293                    | 5                    | insert      | standard      | Delicate Maryland with Cross Serrations      |
| 5293L                   | 5                    | insert      | bariatric     | Delicate Maryland with Cross Serrations      |
| 5294                    | 5                    | insert      | standard      | Johan Forcep                                 |
| 5294L                   | 5                    | insert      | bariatric     | Johan Forcep                                 |
| 5295                    | 5                    | insert      | standard      | Medium Dolphin Nose Dissecting Forcep w/ cup |
| 5295L                   | 5                    | insert      | bariatric     | Medium Dolphin Nose Dissecting Forcep w/ cup |
| 5296                    | 5                    | insert      | standard      | Medium Fenestrated Bowel Grasper             |
| 5296L                   | 5                    | insert      | bariatric     | Medium Fenestrated Bowel Grasper             |
| 5297                    | 5                    | insert      | standard      | Strevy Grasper                               |
| 5297L                   | 5                    | insert      | bariatric     | Strevy Grasper                               |
| 5300                    | 5                    | insert      | standard      | Allis forcep                                 |
| 5300L                   | 5                    | insert      | bariatric     | Allis forcep                                 |
| 5301                    | 5                    | insert      | standard      | Long Allis Forcep                            |
| 5301L                   | 5                    | insert      | bariatric     | Long Allis Forcep                            |
| 5302                    | 5                    | insert      | standard      | Traumatic Grasper 2x3 Teeth                  |
| 5302L                   | 5                    | insert      | bariatric     | Traumatic Grasper 2x3 Teeth                  |
| 5303                    | 5                    | insert      | standard      | Endo Allis Forcep                            |
| 5303L                   | 5                    | insert      | bariatric     | Endo Allis Forcep                            |



| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>                      |
|-------------------------|----------------------|-------------|---------------|--|
| 5304                    | 5                    | insert      | standard      | Glassman Forcep                          |
| 5304L                   | 5                    | insert      | bariatric     | Glassman Forcep                          |
| 5305                    | 5                    | insert      | standard      | Pennington Forcep                        |
| 5305L                   | 5                    | insert      | bariatric     | Pennington Forcep                        |
| 5306                    | 5                    | insert      | standard      | Strong Fenestrated Grasping Forcep       |
| 5306L                   | 5                    | insert      | bariatric     | Strong Fenestrated Grasping Forcep       |
| 5307                    | 5                    | insert      | standard      | McKernan Tri Grasping Fenestrated Forcep |
| 5307L                   | 5                    | insert      | bariatric     | McKernan Tri Grasping Fenestrated Forcep |
| 5308                    | 5                    | insert      | standard      | Alligator Forcep                         |
| 5308L                   | 5                    | insert      | bariatric     | Alligator Forcep                         |
| 5309                    | 5                    | insert      | standard      | Pointed Dissector w/ cup                 |
| 5309L                   | 5                    | insert      | bariatric     | Pointed Dissector w/ cup                 |
| 5310                    | 5                    | insert      | standard      | Round Tip Allis Grasping Forcep          |
| 5310L                   | 5                    | insert      | bariatric     | Round Tip Allis Grasping Forcep          |
| 5311                    | 5                    | insert      | standard      | Curved Dissecting Forcep                 |
| 5311L                   | 5                    | insert      | bariatric     | Curved Dissecting Forcep                 |
| 5312                    | 5                    | insert      | standard      | Short Curved Dissecting Forcep           |
| 5312L                   | 5                    | insert      | bariatric     | Short Curved Dissecting Forcep           |
| 5313                    | 5                    | insert      | standard      | Mixer Dissector                          |
| 5313L                   | 5                    | insert      | bariatric     | Mixer Dissector                          |
| 5314                    | 5                    | insert      | standard      | Duckbill Dissector                       |
| 5314L                   | 5                    | insert      | bariatric     | Duckbill Dissector                       |
| 5315                    | 5                    | insert      | standard      | Straight Tapered Dissector               |

| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>             |
|-------------------------|----------------------|-------------|---------------|---------------------------------|
| 5315L                   | 5                    | insert      | bariatric     | Straight Tapered Dissector      |
| 5316                    | 5                    | insert      | standard      | Straight Mini Dissector         |
| 5316L                   | 5                    | insert      | bariatric     | Straight Mini Dissector         |
| 5317                    | 5                    | insert      | standard      | Mini Right Angle Dissector      |
| 5317L                   | 5                    | insert      | bariatric     | Mini Right Angle Dissector      |
| 5318                    | 5                    | insert      | standard      | Atraumatic Tube Forcep          |
| 5318L                   | 5                    | insert      | bariatric     | Atraumatic Tube Forcep          |
| 5319                    | 5                    | insert      | standard      | Delicate Cone Dissector         |
| 5319L                   | 5                    | insert      | bariatric     | Delicate Cone Dissector         |
| 5320                    | 5                    | insert      | standard      | Micro Dolphin Dissecting Forcep |
| 5320L                   | 5                    | insert      | bariatric     | Micro Dolphin Dissecting Forcep |
| 5321                    | 5                    | insert      | standard      | Claw Forcep 2x3 Teeth           |
| 5321L                   | 5                    | insert      | bariatric     | Claw Forcep 2x3 Teeth           |
| 5322                    | 5                    | insert      | standard      | Biopsy Forcep w/ Two Teeth      |
| 5322L                   | 5                    | insert      | bariatric     | Biopsy Forcep w/ Two Teeth      |
| 5323                    | 5                    | insert      | standard      | Dorsey Fenestrated Grasper      |
| 5323L                   | 5                    | insert      | bariatric     | Dorsey Fenestrated Grasper      |
| 5324                    | 5                    | insert      | standard      | Endo Babcock Forcep             |
| 5324L                   | 5                    | insert      | bariatric     | Endo Babcock Forcep             |
| 5325                    | 5                    | insert      | standard      | Debakey Tissue Forcep           |
| 5325L                   | 5                    | insert      | bariatric     | Debakey Tissue Forcep           |
| 5326                    | 5                    | insert      | standard      | Extracting Forcep Reverse Teeth |
| 5326L                   | 5                    | insert      | bariatric     | Extracting Forcep Reverse Teeth |
| 5327                    | 5                    | insert      | standard      | Grasping Forcep                 |

| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>                   |
|-------------------------|----------------------|-------------|---------------|---------------------------------------|
| 5327L                   | 5                    | insert      | bariatric     | Grasping Forcep                       |
| 5328                    | 5                    | insert      | standard      | Fenestrated Grasping Forcep           |
| 5328L                   | 5                    | insert      | bariatric     | Fenestrated Grasping Forcep           |
| 5329                    | 5                    | insert      | standard      | Micro Dissecting Forcep               |
| 5329L                   | 5                    | insert      | bariatric     | Micro Dissecting Forcep               |
| 5330                    | 5                    | insert      | standard      | Babcock Grasping Forcep               |
| 5330L                   | 5                    | insert      | bariatric     | Babcock Grasping Forcep               |
| 5331                    | 5                    | insert      | standard      | Dolphin Nose Dissecting Forcep w/ cup |
| 5331L                   | 5                    | insert      | bariatric     | Dolphin Nose Dissecting Forcep w/ cup |
| 5332                    | 5                    | insert      | standard      | Cobra Jaw Grasping Forcep             |
| 5332L                   | 5                    | insert      | bariatric     | Cobra Jaw Grasping Forcep             |
| 5333                    | 5                    | insert      | standard      | Atraumatic Grasper                    |
| 5333L                   | 5                    | insert      | bariatric     | Atraumatic Grasper                    |
| 5334                    | 5                    | insert      | standard      | Wave Jaw Grasping Forcep              |
| 5334L                   | 5                    | insert      | bariatric     | Wave Jaw Grasping Forcep              |
| 5335                    | 5                    | insert      | standard      | Paddle Babcock                        |
| 5335L                   | 5                    | insert      | bariatric     | Paddle Babcock                        |
| 5336                    | 5                    | insert      | standard      | Tri-Grasper                           |
| 5336L                   | 5                    | insert      | bariatric     | Tri-Grasper                           |
| 5337                    | 5                    | insert      | standard      | Long Grasping Forcep                  |
| 5337L                   | 5                    | insert      | bariatric     | Long Grasping Forcep                  |
| 5338                    | 5                    | insert      | standard      | Maxi Fenestrated Grasping Forcep      |
| 5338L                   | 5                    | insert      | bariatric     | Maxi Fenestrated Grasping Forcep      |
| 5339                    | 5                    | insert      | standard      | Retrograde Grasping Forcep            |

| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>              |
|-------------------------|----------------------|-------------|---------------|----------------------------------|
| 5339L                   | 5                    | insert      | bariatric     | Retrograde Grasping Forcep       |
| 5340                    | 5                    | insert      | standard      | Kocher Grasping Forcep           |
| 5340L                   | 5                    | insert      | bariatric     | Kocher Grasping Forcep           |
| 5341                    | 5                    | insert      | standard      | Curved Maryland Dissector        |
| 5341L                   | 5                    | insert      | bariatric     | Curved Maryland Dissector        |
| 5342                    | 5                    | insert      | standard      | Dolphin Nose Grasping Forcep     |
| 5342L                   | 5                    | insert      | bariatric     | Dolphin Nose Grasping Forcep     |
| 5343                    | 5                    | insert      | standard      | Micro Dolphin Dissector w/ Cup   |
| 5343L                   | 5                    | insert      | bariatric     | Micro Dolphin Dissector w/ Cup   |
| 5344                    | 5                    | insert      | standard      | Oviduct Atraumatic Forcep        |
| 5344L                   | 5                    | insert      | bariatric     | Oviduct Atraumatic Forcep        |
| 5345                    | 5                    | insert      | standard      | Traumatic Grasper, 2x3 Teeth S/A |
| 5345L                   | 5                    | insert      | bariatric     | Traumatic Grasper, 2x3 Teeth S/A |
| 5346                    | 5                    | insert      | standard      | Atraumatic Grasper S/A           |
| 5346L                   | 5                    | insert      | bariatric     | Atraumatic Grasper S/A           |
| 5347                    | 5                    | insert      | standard      | Grasping Forcep w/ cup           |
| 5347L                   | 5                    | insert      | bariatric     | Grasping Forcep w/ cup           |
| 5348                    | 5                    | insert      | standard      | Ripple Claw Forcep               |
| 5348L                   | 5                    | insert      | bariatric     | Ripple Claw Forcep               |
| 5349                    | 5                    | insert      | standard      | Mini-Micro Dissecting Forcep     |
| 5349L                   | 5                    | insert      | bariatric     | Mini-Micro Dissecting Forcep     |
| 5350                    | 5                    | insert      | standard      | Curved Metz Scissor              |
| 5350L                   | 5                    | insert      | bariatric     | Curved Metz Scissor              |
| 5351                    | 5                    | insert      | standard      | Straight Micro Scissor           |

| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>          |
|-------------------------|----------------------|-------------|---------------|------------------------------|
| 5351L                   | 5                    | insert      | bariatric     | Straight Micro Scissor       |
| 5352                    | 5                    | insert      | standard      | Delicate Curved Metz Scissor |
| 5352L                   | 5                    | insert      | bariatric     | Delicate Curved Metz Scissor |
| 5353                    | 5                    | insert      | standard      | Curved Micro Scissor         |
| 5353L                   | 5                    | insert      | bariatric     | Curved Micro Scissor         |
| 5354                    | 5                    | insert      | standard      | Straight Metz Scissor        |
| 5354L                   | 5                    | insert      | bariatric     | Straight Metz Scissor        |
| 5355                    | 5                    | insert      | standard      | Flat Dissector               |
| 5355L                   | 5                    | insert      | bariatric     | Flat Dissector               |
| 5356                    | 5                    | insert      | standard      | Hook Scissor                 |
| 5356L                   | 5                    | insert      | bariatric     | Hook Scissor                 |
| 5357                    | 5                    | insert      | standard      | Delicate S/A Scissor         |
| 5357L                   | 5                    | insert      | bariatric     | Delicate S/A Scissor         |
| 5358                    | 5                    | insert      | standard      | Serrated Scissor             |
| 5358L                   | 5                    | insert      | bariatric     | Serrated Scissor             |
| 5359                    | 5                    | insert      | standard      | Biopsy Scoop Forcep          |
| 5359L                   | 5                    | insert      | bariatric     | Biopsy Scoop Forcep          |
| 5360                    | 5                    | insert      | standard      | Biopsy Forcep w/ One Tooth   |
| 5360L                   | 5                    | insert      | bariatric     | Biopsy Forcep w/ One Tooth   |
| 5361                    | 5                    | insert      | standard      | Glassman Forcep, 20mm        |
| 5361L                   | 5                    | insert      | bariatric     | Glassman Forcep, 20mm        |
| 5362                    | 5                    | insert      | standard      | Heavy Curved Dissector       |
| 5362L                   | 5                    | insert      | bariatric     | Heavy Curved Dissector       |
| 5363                    | 5                    | insert      | standard      | Dorsey Grasper, 40mm         |

| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>             |
|-------------------------|----------------------|-------------|---------------|---------------------------------|
| 5363L                   | 5                    | insert      | bariatric     | Dorsey Grasper, 40mm            |
| 5364                    | 5                    | insert      | standard      | Tenaculum, 5mm                  |
| 5364L                   | 5                    | insert      | bariatric     | Tenaculum, 5mm                  |
| 5365                    | 5                    | insert      | standard      | Medium Curved Dissector         |
| 5365L                   | 5                    | insert      | bariatric     | Medium Curved Dissector         |
| 5366                    | 5                    | insert      | standard      | Bump Grasper, Single Action     |
| 5366L                   | 5                    | insert      | bariatric     | Bump Grasper, Single Action     |
| 5367                    | 5                    | insert      | standard      | Single Tooth Grasper            |
| 5367L                   | 5                    | insert      | bariatric     | Single Tooth Grasper            |
| 5368                    | 5                    | insert      | standard      | Glassman Forcep, 30mm           |
| 5368L                   | 5                    | insert      | bariatric     | Glassman Forcep, 30mm           |
| 5369                    | 5                    | insert      | standard      | Fenestrated Bowel Grasper, 20mm |
| 5369L                   | 5                    | insert      | bariatric     | Fenestrated Bowel Grasper, 20mm |
| 5370                    | 5                    | insert      | standard      | Single Action Needle Holder     |
| 5370L                   | 5                    | insert      | bariatric     | Single Action Needle Holder     |
| 5371                    | 5                    | insert      | standard      | Suture Knot Pusher              |
| 5371L                   | 5                    | insert      | bariatric     | Suture Knot Pusher              |
| 5372                    | 5                    | insert      | standard      | Credi Curved Dissector          |
| 5372L                   | 5                    | insert      | bariatric     | Credi Curved Dissector          |
| 5373                    | 5                    | insert      | standard      | St. Joseph Dissecting Forcep    |
| 5373L                   | 5                    | insert      | bariatric     | St. Joseph Dissecting Forcep    |
| 5374                    | 5                    | insert      | standard      | Atraumatic Wave Grasper         |
| 5374L                   | 5                    | insert      | bariatric     | Atraumatic Wave Grasper         |
| 5375                    | 5                    | insert      | standard      | Curved Debakey Tissue Forcep    |

| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>                    |
|-------------------------|----------------------|-------------|---------------|--|
| 5375L                   | 5                    | insert      | bariatric     | Curved Debakey Tissue Forcep           |
| 5376                    | 5                    | insert      | standard      | Petrovich Curved Dissector             |
| 5376L                   | 5                    | insert      | bariatric     | Petrovich Curved Dissector             |
| 5377                    | 5                    | insert      | standard      | Andrew Babcock Forcep                  |
| 5377L                   | 5                    | insert      | bariatric     | Andrew Babcock Forcep                  |
| 5378                    | 5                    | insert      | standard      | Maryland with Cross Serrations         |
| 5378L                   | 5                    | insert      | bariatric     | Maryland with Cross Serrations         |
| 5379                    | 5                    | insert      | standard      | Fenestrated Bowel Grasper, 40mm        |
| 5379L                   | 5                    | insert      | bariatric     | Fenestrated Bowel Grasper, 40mm        |
| 5380                    | 5                    | insert      | standard      | Byerley Grasper                        |
| 5380L                   | 5                    | insert      | bariatric     | Byerley Grasper                        |
| 5381                    | 5                    | insert      | standard      | Murray Grasper                         |
| 5381L                   | 5                    | insert      | bariatric     | Murray Grasper                         |
| 5382                    | 5                    | insert      | standard      | Double Action Spoon Forcep, 5mm        |
| 5382L                   | 5                    | insert      | bariatric     | Double Action Spoon Forcep, 5mm        |
| 5383                    | 5                    | insert      | standard      | Biopsy Forcep w/ One Tooth (on bottom) |
| 5383L                   | 5                    | insert      | bariatric     | Biopsy Forcep w/ One Tooth (on bottom) |
| 5384                    | 5                    | insert      | standard      | 5mm Smoot Endo Cinch                   |
| 5384L                   | 5                    | insert      | bariatric     | 5mm Smoot Endo Cinch                   |
| 5385                    | 5                    | insert      | standard      | Single Action Spoon Forcep             |
| 5385L                   | 5                    | insert      | bariatric     | Single Action Spoon Forcep             |
| 5386                    | 5                    | insert      | standard      | Harvey Grasper                         |
| 5386L                   | 5                    | insert      | bariatric     | Harvey Grasper                         |

| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>                               |
|-------------------------|----------------------|-------------|---------------|---|
| 5387                    | 5                    | insert      | standard      | Rodriguez Grasper                                 |
| 5387L                   | 5                    | insert      | bariatric     | Rodriguez Grasper                                 |
| 5388                    | 5                    | insert      | standard      | Forsythe Bump Grasper, Single Action              |
| 5388L                   | 5                    | insert      | bariatric     | Forsythe Bump Grasper, Single Action              |
| 5389                    | 5                    | insert      | standard      | Angled Dissector                                  |
| 5389L                   | 5                    | insert      | bariatric     | Angled Dissector                                  |
| 5390                    | 5                    | insert      | standard      | 5mm Meah Grasper                                  |
| 5390L                   | 5                    | insert      | bariatric     | 5mm Meah Grasper                                  |
| 5391                    | 5                    | insert      | standard      | Kowalski Hunter Bowel Grasper                     |
| 5391L                   | 5                    | insert      | bariatric     | Kowalski Hunter Bowel Grasper                     |
| 5392                    | 5                    | insert      | standard      | Devlin Microfenestrated Grasper                   |
| 5392L                   | 5                    | insert      | bariatric     | Devlin Microfenestrated Grasper                   |
| 5393                    | 5                    | insert      | standard      | Holmes Atraumatic Grasper                         |
| 5393L                   | 5                    | insert      | bariatric     | Holmes Atraumatic Grasper                         |
| 5394                    | 5                    | insert      | standard      | Graves Grasper                                    |
| 5394L                   | 5                    | insert      | bariatric     | Graves Grasper                                    |
| 5395                    | 5                    | insert      | standard      | 5mm Maryland with 90 Degree Tooth                 |
| 5395L                   | 5                    | insert      | bariatric     | 5mm Maryland with 90 Degree Tooth                 |
| SLRVA                   | 5                    | handle/tube | standard      | Take Apart Slide Lock with Rotation               |
| SLRVL                   | 5                    | handle/tube | bariatric     | Take Apart Slide Lock with Rotation               |
| 5SLR                    | 5                    | handle/tube | standard      | Take Apart Slide Lock with Rotation               |
| 5SLRL                   | 5                    | handle/tube | bariatric     | Take Apart Slide Lock with Rotation               |
| 5MRR                    | 5                    | handle/tube | standard      | Monopolar Handle with Rotation, Ratchet on Demand |
| 5MRRL                   | 5                    | handle/tube | bariatric     | Monopolar Handle with Rotation,                   |



| <b>Modular Item #'s</b> | <b>diameter (mm)</b> | <b>Type</b> | <b>Length</b> | <b>Descriptions</b>                                    |
|-------------------------|----------------------|-------------|---------------|--|
|                         |                      |             |               | Ratchet on Demand                                      |
| 5MROT                   | 5                    | handle/tube | standard      | Monopolar Handle with Non-Locking Rotation, NO Ratchet |
| 5MROTL                  | 5                    | handle/tube | bariatric     | Monopolar Handle with Non-Locking Rotation, NO Ratchet |