



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
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 handled instrument and HF 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.	Pajunks 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 3rd 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:

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
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 Forsep w/ cup
5295L	5	insert	bariatric	Medium Dolphin Nose Dissecting Forsep 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

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
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

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
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

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
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

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
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

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
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

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
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

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
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

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
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,

Modular Item #'s	diameter (mm)	Type	Length	Descriptions
				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