



December 20, 2019

Surgical Direct, Inc.
% E. Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K193018

Trade/Device Name: Surgical Direct 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: October 21, 2019
Received: October 29, 2019

Dear E. 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K193018

Device Name

Surgical Direct Hand-held Laparoscopic Instruments

Indications for Use (Describe)

Surgical Direct 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

SPONSOR

Company Name: Surgical Direct, Inc.
Address: 909 South Woodland Blvd.
DeLand, FL 32720
Telephone 386.738.1202 Ext. 222
Email: www.surgicaldirect.com
Contact Person: David Murray
CEO/President

Summary Preparation Date: December 19, 2019

DEVICE NAME

Trade Name: SURGICAL DIRECT 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;

Manufacturer	Brand Name	510(k) Number
ENDOPLUS	ENDOPLUS Hand-held Laparoscopic Instruments	K151567

DEVICE DESCRIPTION

The SURGICAL DIRECT Hand-held Laparoscopic Instruments 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.

INDICATIONS FOR USE

Surgical Direct 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.

INDICATIONS FOR USE COMPARISON TABLE

	SURGICAL DIRECT	ENDOPLUS	Comment
Indications for Use Statement	Surgical Direct 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	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	Same

	SURGICAL DIRECT	ENDOPLUS	Comment
	which it was not intended may result in a damaged or broken instrument.	not intended may result in a damaged or broken instrument.	

PREDICATE PRODUCT COMPARISON TABLE

Parameters	SURGICAL DIRECT	ENDOPLUS	Comments
510(k) Number		K151567	
User Environment	For use by physician in the operating room	For use by physician in the operating room	Same
Monopolar	Yes	Yes	Same
Length	20cm to 50cm	20cm to 50cm	Same
Minimum Cannula Size	5.5cm	5.5cm	Same
Handle Design	Pistol Grip	Pistol Grip	Same
Shaft Rotation	Yes	Yes	Same
Shaft Flexibility	Rigid	Rigid	Same
Shaft Diameter	5mm	5mm	Same
Articulating Component	Does not articulate	Does not articulate	Same
Actuation Mechanism	Handle Operation causes opening and closing of end effector	Handle Operation causes opening and closing of end effector	Same
Flush Port	Yes	Yes	Same
Insertion through trocar	Yes	Yes	Same
Form inserted into trocar	Jaws closed	Jaws closed	Same
Reusable/Disposable	Reusable Handle, Shaft and Insert	Reusable Handle, Shaft and Insert	Same

DISCUSSION OF TECHNOLOGICAL DIFFERENCES

Surgical Direct Hand-held Laparoscopic Instruments are same as the Endoplus Hand held Laparoscopic instruments in indications for use, use environment, user, monopolar, length, minimum cannula size, handle design, shaft rotations, shaft flexibility, shaft diameters,

articulating components, actuation mechanism, flush-port, insertion through trocar, form inserted into trocar, reusable handle, shaft and insert.

There are no differences between the SURGIAL DIRECT and the ENDOPLUS hand-held laparoscopic instruments.

PERFORMANCE DATA

Safety Testing:

- 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
- EMC Validation Test

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

CLINICAL STUDY

No clinical study was conducted.

CONCLUSION

Surgical Direct Hand-held Laparoscopic Instruments has an identical indication for use and identical technological characteristics as the predicate device. Biocompatibility testing, electrical testing and other performance tests were conducted to verify safe and effective use. Surgical Direct concludes that the Surgical Direct 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

Surgical Direct #	(mm)	Type	Length	Descriptions
SD8901	5	insert	Std	Dolphin Nose Dissecting Forceps w/ cup
SD890145	5	insert	Bari	Dolphin Nose Dissecting Forceps w/ cup
SD8902	5	insert	Std	Curved Dissecting Forceps
SD890245	5	insert	Bari	Curved Dissecting Forceps
SD8903	5	insert	Std	Micro Dolphin Dissector w/ Cup
SD890345	5	insert	Bari	Micro Dolphin Dissector w/ Cup
SD8904	5	insert	Std	Short Curved Dissecting Forceps
SD890445	5	insert	Bari	Short Curved Dissecting Forceps
SD8905	5	insert	Std	Micro Dolphin Dissecting Forceps
SD890545	5	insert	Bari	Micro Dolphin Dissecting Forceps
SD8906	5	insert	Std	Fenestrated Grasping Forceps
SD890645	5	insert	Bari	Fenestrated Grasping Forceps
SD8907	5	insert	Std	Delicate Cone Dissector
SD890745	5	insert	Bari	Delicate Cone Dissector
SD8908	5	insert	Std	Alligator Forceps
SD890845	5	insert	Bari	Alligator Forceps
SD8909	5	insert	Std	Dolphin Nose Grasping Forceps
SD890945	5	insert	Bari	Dolphin Nose Grasping Forceps

Surgical Direct #	(mm)	Type	Length	Descriptions
SD8910	5	insert	Std	Strong Fenestrated Grasping Forceps
SD891045	5	insert	Bari	Strong Fenestrated Grasping Forceps
SD8911	5	insert	Std	Maxi Fenestrated Grasping Forceps
SD891145	5	insert	Bari	Maxi Fenestrated Grasping Forceps
SD8912	5	insert	Std	Duckbill Dissector
SD891245	5	insert	Bari	Duckbill Dissector
SD8913	5	insert	Std	Curved Maryland Dissector
SD891345	5	insert	Bari	Curved Maryland Dissector
SD8914	5	insert	Std	Flat Dissector
SD891445	5	insert	Bari	Flat Dissector
SD8915	5	insert	Std	Straight Tapered Dissector
SD891545	5	insert	Bari	Straight Tapered Dissector
SD8916	5	insert	Std	Mini-Micro Dissecting Forceps
SD891645	5	insert	Bari	Mini-Micro Dissecting Forceps
SD8917	5	insert	Std	Mixer Dissector
SD891745	5	insert	Bari	Mixer Dissector
SD8918	5	insert	Std	Micro Dissecting Forceps
SD891845	5	insert	Bari	Micro Dissecting Forceps
SD8919	5	insert	Std	Mini Right-Angle Dissector
SD891945	5	insert	Bari	Mini Right-Angle Dissector
SD8920	5	insert	Std	Straight Mini Dissector
SD892045	5	insert	Bari	Straight Mini Dissector
SD8921	5	insert	Std	Pointed Dissector w/ cup
SD892145	5	insert	Bari	Pointed Dissector w/ cup
SD8922	5	insert	Std	Atraumatic Grasper S/A
SD892245	5	insert	Bari	Atraumatic Grasper S/A
SD8923	5	insert	Std	Atraumatic Grasper
SD892345	5	insert	Bari	Atraumatic Grasper
SD8924	5	insert	Std	Extracting Forceps Reverse Teeth
SD892445	5	insert	Bari	Extracting Forceps Reverse Teeth
SD8925	5	insert	Std	Traumatic Grasper 2x3 Teeth
SD892545	5	insert	Bari	Traumatic Grasper 2x3 Teeth
SD8926	5	insert	Std	Cobra Jaw Grasping Forceps
SD892645	5	insert	Bari	Cobra Jaw Grasping Forceps
SD8927	5	insert	Std	Claw Forceps 2x3 Teeth
SD892745	5	insert	Bari	Claw Forceps 2x3 Teeth

Surgical Direct #	(mm)	Type	Length	Descriptions
SD8928	5	insert	Std	Glassman Forceps, 20mm
SD892845	5	insert	Bari	Glassman Forceps, 20mm
SD8929	5	insert	Std	Traumatic Grasper, 2x3 Teeth S/A
SD892945	5	insert	Bari	Traumatic Grasper, 2x3 Teeth S/A
SD8930	5	insert	Std	Retrograde Grasping Forceps
SD893045	5	insert	Bari	Retrograde Grasping Forceps
SD8931	5	insert	Std	Ripple Claw Forceps
SD893145	5	insert	Bari	Ripple Claw Forceps
SD8932	5	insert	Std	Grasping Forceps
SD893245	5	insert	Bari	Grasping Forceps
SD8933	5	insert	Std	Grasping Forceps w/ cup
SD893345	5	insert	Bari	Grasping Forceps w/ cup
SD8934	5	insert	Std	Long Grasping Forceps
SD893445	5	insert	Bari	Long Grasping Forceps
SD8935	5	insert	Std	Oviduct Atraumatic Forceps
SD893545	5	insert	Bari	Oviduct Atraumatic Forceps
SD8936	5	insert	Std	McKernan Tri Grasping Fenestrated Forceps
SD893645	5	insert	Bari	McKernan Tri Grasping Fenestrated Forceps
SD8937	5	insert	Std	Tri-Grasper
SD893745	5	insert	Bari	Tri-Grasper
SD8938	5	insert	Std	Atraumatic Tube Forceps
SD893845	5	insert	Bari	Atraumatic Tube Forceps
SD8939	5	insert	Std	Wave Jaw Grasping Forceps
SD893945	5	insert	Bari	Wave Jaw Grasping Forceps
SD8940	5	insert	Std	Allis forceps
SD894045	5	insert	Bari	Allis forceps
SD8941	5	insert	Std	Rodriguez Grasper
SD894145	5	insert	Bari	Rodriguez Grasper
SD8942	5	insert	Std	Angled Dissector
SD894245	5	insert	Bari	Angled Dissector
SD8943	5	insert	Std	Biopsy Forceps w/ Two Teeth
SD894345	5	insert	Bari	Biopsy Forceps w/ Two Teeth
SD8944	5	insert	Std	Forsythe Bump Grasper, Single Action
SD894445	5	insert	Bari	Forsythe Bump Grasper, Single Action
SD8945	5	insert	Std	Babcock Grasping Forceps
SD894545	5	insert	Bari	Babcock Grasping Forceps

Surgical Direct #	(mm)	Type	Length	Descriptions
SD8946	5	insert	Std	Long Allis Forceps
SD894645	5	insert	Bari	Long Allis Forceps
SD8947	5	insert	Std	Endo Babcock Forceps
SD894745	5	insert	Bari	Endo Babcock Forceps
SD8948	5	insert	Std	Paddle Babcock
SD894845	5	insert	Bari	Paddle Babcock
SD8949	5	insert	Std	Debakey Tissue Forceps
SD894945	5	insert	Bari	Debakey Tissue Forceps
SD8950	5	insert	Std	Dorsey Fenestrated Grasper
SD895045	5	insert	Bari	Dorsey Fenestrated Grasper
SD8951	5	insert	Std	Glassman Forceps
SD895145	5	insert	Bari	Glassman Forceps
SD8953	5	insert	Std	Round Tip Allis Grasping Forceps
SD895345	5	insert	Bari	Round Tip Allis Grasping Forceps
SD8956	5	insert	Std	Medium Fenestrated Bowel Grasper
SD895645	5	insert	Bari	Medium Fenestrated Bowel Grasper
SD8957	5	insert	Std	Endo Allis Forceps
SD895745	5	insert	Bari	Endo Allis Forceps
SD8958	5	insert	Std	Pennington Forceps
SD895845	5	insert	Bari	Pennington Forceps
SD8959	5	insert	Std	Atraumatic Wave Grasper
SD895945	5	insert	Bari	Atraumatic Wave Grasper
SD8960	5	insert	Std	Kocher Grasping Forceps
SD896045	5	insert	Bari	Kocher Grasping Forceps
SD8961	5	insert	Std	Curved Metz Scissor
SD896145	5	insert	Bari	Curved Metz Scissor
SD8962	5	insert	Std	Straight Micro Scissor
SD896245	5	insert	Bari	Straight Micro Scissor
SD8963	5	insert	Std	Delicate Curved Metz Scissor
SD896345	5	insert	Bari	Delicate Curved Metz Scissor
SD8964	5	insert	Std	Curved Micro Scissor
SD896445	5	insert	Bari	Curved Micro Scissor
SD8965	5	insert	Std	Straight Metz Scissor
SD896545	5	insert	Bari	Straight Metz Scissor
SD8966	5	insert	Std	Hook Scissor
SD896645	5	insert	Bari	Hook Scissor

Surgical Direct #	(mm)	Type	Length	Descriptions
SD8967	5	insert	Std	Delicate S/A Scissor
SD896745	5	insert	Bari	Delicate S/A Scissor
SD8968	5	insert	Std	Serrated Scissor
SD896845	5	insert	Bari	Serrated Scissor
SD8969	5	insert	Std	Biopsy Scoop Forceps
SD896945	5	insert	Bari	Biopsy Scoop Forceps
SD8970	5	insert	Std	Biopsy Forceps w/ One Tooth
SD897045	5	insert	Bari	Biopsy Forceps w/ One Tooth
SD8971	5	insert	Std	Dorsey Grasper, 40mm
SD897145	5	insert	Bari	Dorsey Grasper, 40mm
SD8972	5	insert	Std	Single Tooth Grasper
SD897245	5	insert	Bari	Single Tooth Grasper
SD8973	5	insert	Std	Glassman Forceps, 30mm
SD897345	5	insert	Bari	Glassman Forceps, 30mm
SD8974	5	insert	Std	Single Action Needle Holder
SD897445	5	insert	Bari	Single Action Needle Holder
SD8975	5	insert	Std	Suture Knot Pusher
SD897545	5	insert	Bari	Suture Knot Pusher
SD8976	5	insert	Std	Credi Curved Dissector
SD897645	5	insert	Bari	Credi Curved Dissector
SD8977	5	insert	Std	St. Joseph Dissecting Forceps
SD897745	5	insert	Bari	St. Joseph Dissecting Forceps
SD8978	5	insert	Std	Curved Debakey Tissue Forceps
SD897845	5	insert	Bari	Curved Debakey Tissue Forceps
SD8979	5	insert	Std	Petrovich Curved Dissector
SD897945	5	insert	Bari	Petrovich Curved Dissector
SD8980	5	insert	Std	Fenestrated Bowel Grasper, 40mm
SD898045	5	insert	Bari	Fenestrated Bowel Grasper, 40mm
SD8981	5	insert	Std	Byerley Grasper
SD898145	5	insert	Bari	Byerley Grasper
SD8982	5	insert	Std	Murray Grasper
SD898245	5	insert	Bari	Murray Grasper
SD8983	5	insert	Std	Fenestrated Bowel Grasper, 20mm
SD898345	5	insert	Bari	Fenestrated Bowel Grasper, 20mm
SD8984	5	insert	Std	Bump Grasper, Single Action
SD898445	5	insert	Bari	Bump Grasper, Single Action

Surgical Direct #	(mm)	Type	Length	Descriptions
SD8985	5	insert	Std	Double Action Spoon Forceps, 5mm
SD898545	5	insert	Bari	Double Action Spoon Forceps, 5mm
SD8986	5	insert	Std	Biopsy Forceps w/ One Tooth (on bottom)
SD898645	5	insert	Bari	Biopsy Forceps w/ One Tooth (on bottom)
SD8987	5	insert	Std	5mm Smoot Endo Cinch
SD898745	5	insert	Bari	5mm Smoot Endo Cinch
SD8988	5	insert	Std	Andrew Babcock Forceps
SD898845	5	insert	Bari	Andrew Babcock Forceps
SD8989	5	insert	Std	Tenaculum, 5mm
SD898945	5	insert	Bari	Tenaculum, 5mm
SD8990	5	insert	Std	Maryland with Cross Serrations
SD899045	5	insert	Bari	Maryland with Cross Serrations
SD8991	5	insert	Std	Single Action Spoon Forceps
SD899145	5	insert	Bari	Single Action Spoon Forceps
SD8992	5	insert	Std	Harvey Grasper
SD899245	5	insert	Bari	Harvey Grasper
SD8993	5	insert	Std	5mm Meah Grasper
SD899345	5	insert	Bari	5mm Meah Grasper
SD8994	5	insert	Std	Strevy Grasper
SD899445	5	insert	Bari	Strevy Grasper
SD8995	5	insert	Std	Medium Curved Dissector
SD899545	5	insert	Bari	Medium Curved Dissector
SD8996	5	insert	Std	Heavy Curved Dissector
SD899645	5	insert	Bari	Heavy Curved Dissector
SD8997	5	insert	Std	Johan Forceps
SD899745	5	insert	Bari	Johan Forceps
SD8998	5	insert	Std	Delicate Maryland with Cross Serrations
SD899845	5	insert	Bari	Delicate Maryland with Cross Serrations
SD8999	5	insert	Std	Medium Dolphin Nose Dissecting Forceps w/ cup
SD899945	5	insert	Bari	Medium Dolphin Nose Dissecting Forceps w/ cup
SD902	5	handle/tube	Std	Monopolar Handle with Rotation, Ratchet on Demand
SD903	5	handle/tube	Bari	Monopolar Handle with Rotation, Ratchet on Demand
SD904	5	handle/tube	Std	Take Apart Slide Lock with Rotation
SD905	5	handle/tube	Bari	Take Apart Slide Lock with Rotation
SD908	5	handle/tube	Std	Monopolar Handle with Non-Locking Rotation, NO Ratchet

Surgical Direct #	(mm)	Type	Length	Descriptions
SD909	5	handle/tube	Bari	Monopolar Handle with Non-Locking Rotation, NO Ratchet
SD910	5	handle/tube	Std	Take Apart Slide Lock with Rotation
SD911	5	handle/tube	Bari	Take Apart Slide Lock with Rotation
SD9901	5	insert	Std	Kowalski Hunter Bowel Grasper
SD990145	5	insert	Bari	Kowalski Hunter Bowel Grasper
SD9902	5	insert	Std	Devlin Micro-fenestrated Grasper
SD990245	5	insert	Bari	Devlin Micro-fenestrated Grasper
SD9903	5	insert	Std	Holmes Atraumatic Grasper
SD990345	5	insert	Bari	Holmes Atraumatic Grasper
SD9904	5	insert	Std	Graves Grasper
SD990445	5	insert	Bari	Graves Grasper
SD9905	5	insert	Std	5mm Maryland with 90 Degree Tooth
SD990545	5	insert	Bari	5mm Maryland with 90 Degree Tooth