November 20, 2023

HG Innovations Ltd
℅ Wondwossen Tekolla
Associate Regulatory Consultant
Medical Device Academy, Inc
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K233346
Trade/Device Name: Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 180mm, 0.5mm Tip with Cable (HMAL18/005); Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 180mm, 1.0mm Tip with Cable (HMAL18/010); Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 180mm, 1.5mm Tip with Cable (HMAL18/015); Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 200mm, 0.5mm Tip with Cable (HMAL20/005); Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 200mm, 1.0mm Tip with Cable (HMAL20/010); Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 200mm, 1.5mm Tip with Cable (HMAL20/015); Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 230mm, 0.5mm Tip with Cable (HMAL23/005); Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 230mm, 1.0mm Tip with Cable (HMAL23/010); Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 230mm, 1.5mm Tip with Cable (HMAL23/015); Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 180mm, 0.5mm Tip with Cable & Irrigation Tubing (H
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 15, 2023
Received: September 29, 2023

Dear Wondwossen Tekolla:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.11.20 13:08:27 -05'00'

Mark Trumbore, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233346

Device Name

Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 180mm, 0.5mm Tip with Cable (HMAL18/005);
Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 180mm, 1.0mm Tip with Cable (HMAL18/010);
Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 180mm, 1.5mm Tip with Cable (HMAL18/015);
Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 200mm, 0.5mm Tip with Cable (HMAL20/005);
Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 200mm, 1.0mm Tip with Cable (HMAL20/010);
Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 200mm, 1.5mm Tip with Cable (HMAL20/015);
Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 230mm, 0.5mm Tip with Cable (HMAL23/005);
Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 230mm, 1.0mm Tip with Cable (HMAL23/010);
Heinrich Single Use Non-Stick Bayonet Bipolar Forceps, 230mm, 1.5mm Tip with Cable (HMAL23/015);
Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 180mm, 0.5mm Tip with Cable & Irrigation Tubing (HMAL18/005/IRD);
Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 180mm, 1.0mm Tip with Cable & Irrigation Tubing (HMAL18/010/IRD);
Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 180mm, 1.5mm Tip with Cable & Irrigation Tubing (HMAL18/015/IRD);
Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 200mm, 0.5mm Tip with Cable & Irrigation Tubing (HMAL20/005/IRD);
Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 200mm, 1.0mm Tip with Cable & Irrigation Tubing (HMAL20/010/IRD);
Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 200mm, 1.5mm Tip with Cable & Irrigation Tubing (HMAL20/015/IRD);
Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 230mm, 0.5mm Tip with Cable & Irrigation Tubing (HMAL23/005/IRD);
Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 230mm, 1.0mm Tip with Cable & Irrigation Tubing (HMAL23/010/IRD);
Heinrich Single Use Non-Stick, Irrigating Bayonet Bipolar Forceps, 230mm, 1.5mm Tip with Cable & Irrigation Tubing (HMAL23/015/IRD)

Indications for Use *(Describe)*

Heinrich Single-use non-stick bipolar forceps and single-use non-stick irrigating bipolar forceps are intended for use by a physician familiar with electrosurgery for bipolar coagulation and irrigation of tissue for general open surgery where coagulation of soft tissue is needed. Heinrich Single-use non-stick bipolar forceps and single-use non-stick irrigating bipolar forceps must be operated within the following parameters:
-Frequency range between 300 kHz-1,000 kHZ;
-Maximum generator operating voltage 600Vp.

Single-use non-stick bipolar forceps and single-use non-stick irrigating bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures. The types of surgery intended include:

-ENT
-Gynecology
-Urology
-General Surgery
-Neurosurgery
-Laryngeal Surgery
-Orthopedic Surgery
-Thoracic Surgery

Single-use non-stick bipolar forceps and single-use non-stick irrigating bipolar forceps are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Single-use non-stick bipolar forceps and single-use non-stick irrigating bipolar forceps must only be used with a bipolar coagulation current.

HG Innovations, as a manufacturer, does not recommend a specific procedure.

Use of bipolar techniques may be desirable in order to avoid unwanted tissue damage for surgical procedures where HF current could flow through relatively small cross-sectional area of body.

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.

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER: Mr. Wondwossen Tekolla
Company Name: Medical Device Academy Inc.
Address: 345 Lincoln Hill Rd
City, State, Zip USA Shrewsbury, VT 05738
Tel: 919-903-0194
Fax: N/A

Contact Person: Dr. M Umran Rafiq
Date Prepared: August 23, 2023

II. DEVICE

Device Trade Name: *Heinrich Single Use Non-Stick Bipolar Forceps/ Heinrich Single Use Irrigating Non-Stick Bipolar Forceps*
Classification Name: Electrosurgical Cutting & Coagulation Device and Accessories
Regulation: *21 CFR §*878.4400
Regulatory Class: Class II
Device Panel: General & Plastic Surgery
Product Classification Code: GEI

III. PREDICATE DEVICE

A) Predicate 1: Irrigating forceps.
Predicate Manufacturer: Synergetics, Inc.
Predicate Trade Name: Synergetics Disposable Single Use Dual Irrigating Standard Bipolar Forceps
Predicate 510(k): *K110924*

B) *Predicate 2: Non-irrigating forceps*
Predicate Manufacturer: Sutter Medizintechnik GmbH
Predicate Trade Name: Sutter Swyng® Nonstick Bipolar Forceps- Single Use
Predicate 510(k): *K193587*

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

HG Innovations Ltd.'s electrical surgical instruments encompass a wide variety of instruments that are widely used in the medical industry. Electrosurgical forceps and electrodes have been used in surgery for many years. The single-use, non-stick bipolar forceps and non-stick bipolar irrigating forceps (various sizes and tip configurations), with preattached cables are designed to grasp, manipulate, coagulate and irrigate soft

tissues and are intended for use by a physician familiar with electrosurgery in bipolar coagulation for general open surgery where coagulation of soft tissue is needed. The blood vessel or tissue is grasped between the forceps tines, each of which acts as an electrode, and current passes to desiccate and coagulate the tissue. Bipolar forceps are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. The bipolar forceps must be operated with the following parameters:
-Frequency range between 300 kHz-1,000 kHZ;
-Maximum generator operating voltage 600Vp.

V. INDICATIONS FOR USE

Heinrich single-use non-stick bipolar forceps and Heinrich single-use non-stick irrigating bipolar forceps are intended for use by a physician familiar with electrosurgery for bipolar coagulation and irrigation of tissue for general open surgery where coagulation of soft tissue is needed. Heinrich single-use non-stick bipolar forceps and Heinrich single-use non-stick irrigating bipolar forceps must be operated within the following parameters:
-Frequency range between 300 kHz-1,000 kHZ;
-Maximum generator operating voltage 600Vp.

Heinrich Single-use non-stick bipolar forceps and Heinrich single-use non-stick irrigating bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures. The types of surgery intended include:

-ENT
-Gynecology
-Urology
-General Surgery
-Neurosurgery
-Laryngeal Surgery
-Orthopedic Surgery
-Thoracic Surgery

Heinrich Single-use non-stick bipolar forceps and Heinrich single-use non-stick irrigating bipolar forceps are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Heinrich single-use non-stick bipolar forceps and Heinrich single-use non-stick irrigating bipolar forceps must only be used with a bipolar coagulation current.

HG Innovations, as a manufacturer, does not recommend a specific procedure.

Use of bipolar techniques may be desirable in order to avoid unwanted tissue damage for surgical procedures where HF current could flow through relatively small cross-sectional area of body.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE & PERFORMANCE DATA

Table 1: Comparison of subject device, Heinrich Single Use Non-Stick Irrigating Bipolar Forceps with Cable with predicate device, Synergetics Disposable Single Use Dual Irrigating Standard Bipolar Forceps- K110924

Feature	Subject Device	Predicate Device	Justification For Differences
	Heinrich Single Use Non-Stick Irrigating Bipolar Forceps with Cable (one model with different sizes)	Synergetics Disposable Single Use Dual Irrigating Standard Bipolar Forceps K110924	
Manufacturer	HG Innovations Ltd.	Synergetics, Inc	--------
Regulation	878.4400	878.4400	Same
Classification 21	Class II	Class II	Same
Product Code	GEI	GEI	Same
Device Description	The Heinrich single-use, non-stick irrigating bipolar forceps (various sizes), with preattached cables are designed to grasp, manipulate, coagulate and irrigate soft tissues and are intended for use by a physician familiar with electrosurgery in bipolar coagulation for general open surgery where coagulation of soft tissue is needed. The blood vessel or tissue is grasped between the forceps tines, each of which acts as an electrode, and current passes to desiccate and coagulate the tissue. Bipolar forceps are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar	The SynergeticsTm Disposable Spetzlefrm Malis® Standard Bipolar Forceps are sterile single use devices for use in electrosurgeiy. The forceps are a bayonet style and include a cord at the proximal end which allows for connection to a Malis bipolar electrosurgical generator.	Similar

	forceps must only be used with bipolar coagulation current.		
Indications for use	Heinrich single-use non-stick irrigating bipolar forceps are intended for use by a physician familiar with electrosurgery for bipolar coagulation and irrigation of tissue for general open surgery where coagulation of soft tissue is needed. Heinrich single-use non-stick irrigating bipolar forceps must be operated within the following parameters: -Frequency range between 300 kHz-1,000 kHZ; -Maximum generator operating voltage 600Vp. Heinrich single-use non-stick irrigating bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures. The types of surgery intended include:	Sterile, single use, for use in electrosurgery for coagulation and irrigation of tissue.	Same

	-ENT -Gynecology -Urology -General Surgery -Neurosurgery -Laryngeal Surgery -Orthopedic Surgery -Thoracic Surgery Heinrich single-use non-stick irrigating bipolar forceps are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Heinrich single-use non-stick bipolar forceps and Heinrich single-use non-stick irrigating bipolar forceps must only be used with a bipolar coagulation current. HG Innovations, as a manufacturer, does not recommend a specific procedure. Use of bipolar techniques may be desirable in order to avoid unwanted tissue damage for surgical procedures where HF current could flow through relatively small cross-sectional area of body.		

For Use with	Electrosurgical generators, irrigation modules and irrigation tubing	Electrosurgical generators, irrigation modules and irrigation tubing	Same
Irrigation Tube Connection	Connects to irrigation port that's connected to main housing	Connects to irrigation port that's connected to main housing	Similar
Delivery Line to distal end of forceps	Yes	Yes	Same
Irrigation Pipe	PVC, silicone	N/A	
Rx/ OTC	Rx	Rx	Same
Design	Bayonet	Bayonet	Same
Energy Source	Generator	Generator	Same
Single Use	Yes	Yes	Same. Disposable use of subject device reduces risk.
Electrode Type	Bipolar	Bipolar	Same
Tip Sizes	0.5mm, 1mm, 1.5mm	0.5mm, 1mm, 1.5mm	Range of tip sizes is identical. Larger tip will decrease current density and last longer than smaller tips.
Lengths	180mm, 200mm, 230mm	177.8mm-228.6mm ** Tip and length sizes obtained from marketing brochure	Range of lengths is similar and largely overlaps with predicate device.
Component Materials			
Forceps' Tip(s)	Silver Plated	Silver Plated	Forceps tip materials are identical
Arm Material	Aluminum	Aluminum	Forceps arm materials are identical
Outer Cap	Polypropylene, SABIC® PP 107M90T + Master Colour, Black	N/A	N/A
Cable	Polyvinyl Cholride (PVC), 2/16 core, Copper Wires	N/A	Both are made of plastic
Solder	Tin	N/A	N/A

Powder Coating	Nylon Powder, Polyamide 11	PVDF	Both are made of plastic and are non patient contacting
Colorant	Pigment Blue 15:3 UN8632	N/A	N/A
Forging Blank	Aluminum	N/A	N/A
Inner Cap	Polypropylene, SABIC® PP 107M90T + Master Colour, Black	N/A	N/A
Banana Pin	Chrome-plated, Gold plated spring, Brass	N/A	N/A
Internal Plug Body	Polypropylene, SABIC® PP 107M90T + Master Colour, Black	N/A	N/A
Outer Plug Body	Polyvinyl Chloride (PVC)	N/A	Both are made of plastic
Sterility Testing (ISO-10993-7)	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same.
Shelf-Life Testing	Real-time aging study shows product shelf life up to 3 years	N/A	N/A
Performance Testing			
Biocompatibility (ISO10993-1)	Pass	N/A	Subject devices is demonstrably non-cytotoxic, non-irritating, systemically non toxic, non-sensitizing and passes pyrogenicity testing. Predicate device has not reported biocompatibility testing.
Electrical Safety & EMC (AAMI/ANSI IEC 60601-1, IEC 60601-2-2)	Pass	Pass	Subject device and predicate device both passed electromagnetic compatibility testing and electrical safety testing which includes mechanical strength and functionality testing.

Table 2: Comparison of subject device, Single Use Non-Stick Bipolar Forceps with with predicate device, Sutter Swyng® Nonstick Bipolar Forceps, Single-use – *K193587*

Feature	Subject Device	Predicate Device	Justification For Differences
	Heinrich Single Use Non-Stick Bipolar Forceps with Cable – (one model with different sizes)	Sutter Swyng® nonstick bipolar forceps, single-use – *K193587*	
Manufacturer	HG Innovations Ltd.	Sutter Medizintechnik GmbH	--------
Regulation	878.4400	878.4400	Same
Classification 21	Class II	Class II	Same
Product Code	GEI	GEI	Same
Device Description	The Heinrich single-use, non-stick bipolar forceps (various sizes and tip configurations), with preattached cables are designed to grasp, manipulate, coagulate soft tissues and are intended for use by a physician familiar with electrosurgery in bipolar coagulation for general open surgery where coagulation of soft tissue is needed. The blood vessel or tissue is grasped between the forceps tines, each of which acts as an electrode, and current passes to desiccate and coagulate the tissue. Bipolar forceps are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar forceps must only be	Sutter Swyng® non-stick bipolar forceps, single-use are electrosurgical instruments. The bipolar forceps are provided with bayonet-style handle design with straight or angled tips and different total lengths. They are to be connected through an appropriate bipolar cable with the bipolar output of an electrosurgical generator. The electrodes are provided sterile and are single-use instruments.	Similar

	used with bipolar coagulation current.		
Indications for use	Heinrich Single-use non-stick bipolar forceps are intended for use by a physician familiar with electrosurgery for bipolar coagulation of tissue for general open surgery where coagulation of soft tissue is needed. Heinrich single-use non-stick bipolar forceps must be operated within the following parameters: -Frequency range between 300 kHz-1,000 kHZ; -Maximum generator operating voltage 600Vp. Heinrich single-use non-stick bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures. The types of surgery intended include: -ENT -Gynecology -Urology -General Surgery -Neurosurgery -Laryngeal Surgery -Orthopedic Surgery -Thoracic Surgery	Sutter Swyng® non-stick bipolar forceps, single-use are intended for use in electrosurgery for coagulation of tissue.	Same

	Heinrich Single-use non-stick bipolar forceps are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Heinrich single-use non-stick bipolar forceps must only be used with a bipolar coagulation current. HG Innovations, as a manufacturer, does not recommend a specific procedure. Use of bipolar techniques may be desirable in order to avoid unwanted tissue damage for surgical procedures where HF current could flow through relatively small cross-sectional area of body.		
Rx/ OTC	Rx	Rx	Same
Design	Bayonet	Bayonet	Same
Energy Source	Generator	Generator	Same
Single Use	Yes	Yes	Same. Disposable use of subject device reduces risk.
Maximum Peak Voltage	600 Vp	500 Vp	Although subject device has a slightly higher maximum voltage, it has duly passed electrical safety testing and therefore, the higher max voltage does not raise any questions of device safety.
Electrode Type	Bipolar	Bipolar	Same

Tip Sizes	0.5mm, 1mm, 1.5mm	0.5mm, 1mm, 1.5mm	Range of tip sizes is identical. Larger tip will decrease current density and last longer than smaller tips.
Lengths	180mm, 200mm, 230mm	Different lengths, specifics N/A	N/A
Component Materials			
Forceps' Tip(s)	Silver and Rhodium Plated	Silver and Rhodium Plated	Forceps tip materials are identical
Arm Material	Aluminum	Aluminum	Forceps arm materials are identical
Outer Cap	Polypropylene, SABIC® PP 107M90T + Master Colour, Black	N/A	N/A
Cable	Polyvinyl Cholride (PVC), 2/16 core, Copper Wires	N/A	Both are made of plastic
Solder	Tin	N/A	N/A
Powder Coating	Nylon Powder, Polyamide 11	Polyamide	Similar
Colorant	Pigment Blue 15:3 UN8632	N/A	N/A
Forging Blank	Aluminum	N/A	N/A
Inner Cap	Polypropylene, SABIC® PP 107M90T + Master Colour, Black	N/A	N/A
Banana Pin	Chrome-plated, Gold plated spring, Brass	N/A	N/A
Internal Plug Body	Polypropylene, SABIC® PP 107M90T + Master Colour, Black	N/A	N/A
Outer Plug Body	Polyvinyl Chloride (PVC)	N/A	Both are made of plastic
Sterility Testing (ISO-10993-7)	Ethylene Oxide (EO)	Gamma Irradiation	Both are recognized sterility methods.
Shelf-Life Testing	Real-time aging study shows product shelf life up to 3 years	aging study established product shelf life up to 3 years	Identical
Performance Testing			

Biocompatibility (ISO10993-1)	Pass	Pass	Subject devices is demonstrably non-cytotoxic, non-irritating, systemically non toxic, non-sensitizing and passes pyrogenicity testing. Predicate device specifics not available, but has passed biocompatibility testing.
Electrical Safety & EMC (AAMI/ANSI IEC 60601-1, IEC 60601-2-2)	Pass	Pass	Subject device and predicate device both passed electromagnetic compatibility testing and electrical safety testing which includes mechanical strength and functionality testing.

Bench Performance Testing
System Testing
HG Innovation's bipolar forceps are identical to the predicate device in their intended use/indications for use and materials used for the arms, and tips. No further testing necessary.

Software Verification and Validation Testing
N/A

Mechanical and acoustic Testing
N/A

Animal Study
N/A

Human Clinical Performance Testing
N/A

VII. CONCLUSION
Based on the indications for use, technological characteristics and comparison with the predicate devices, the subject devices have demonstrated substantial equivalence.