November 20, 2023

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

Re: K233351
Trade/Device Name: Single Use Non-Stick McPherson Bipolar Forceps, 110mm, 0.5mm Tip with Cable (HNSAG-5110M); Single Use Non-Stick Jeweller Bipolar Forceps, 115mm, 0.5mm Tip with Cable (HNSAG-5115J); Single Use Non-Stick Jeweller Bipolar Forceps, 115mm, 1.0mm Tip with Cable (HNSAG-1115J); Single Use Non-Stick Adson Bipolar Forceps, 120mm, 1.0mm Tip with Cable (HNSAG-1120A); Single Use Non-Stick Adson Bipolar Forceps, 120mm, 0.5mm Tip with Cable (HNSAG-5120A); Single Use Non-Stick Adson Bipolar Forceps, 150mm, 1.0mm Tip with Cable (HNSAG-1150A); Single Use Non-Stick Straight Bipolar Forceps, 150mm, 0.5mm Tip with Cable (HNSAG-5150S); Single Use Non-Stick Straight Bipolar Forceps, 150mm, 1.0mm Tip with Cable (HNSAG-1150S); Single Use Non-Stick Straight Bipolar Forceps, 160mm, 0.5mm Tip with Cable (HNSAG-5160S); Single Use Non-Stick Straight Bipolar Forceps, 160mm, 1.0mm Tip with Cable (HNSAG-1160S); Single Use Non-Stick Straight Bipolar Forceps, 180mm, 0.5mm Tip with Cable (HNSAG-5180S); Single
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 29, 2023
Received: September 29, 2023

Dear Wondwossem 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 13:04:01 -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)*

K233351

Device Name

Single Use Non-Stick McPherson Bipolar Forceps, 110mm, 0.5mm Tip with Cable (HNSAG-5110M);
Single Use Non-Stick Jeweller Bipolar Forceps, 115mm, 0.5mm Tip with Cable (HNSAG-5115J);
Single Use Non-Stick Jeweller Bipolar Forceps, 115mm, 1.0mm Tip with Cable (HNSAG-1115J);
Single Use Non-Stick Adson Bipolar Forceps, 120mm, 1.0mm Tip with Cable (HNSAG-1120A);
Single Use Non-Stick Adson Bipolar Forceps, 120mm, 0.5mm Tip with Cable (HNSAG-5120A);
Single Use Non-Stick Adson Bipolar Forceps, 150mm, 1.0mm Tip with Cable (HNSAG-1150A);
Single Use Non-Stick Straight Bipolar Forceps, 150mm, 0.5mm Tip with Cable (HNSAG-5150S);
Single Use Non-Stick Straight Bipolar Forceps, 150mm, 1.0mm Tip with Cable (HNSAG-1150S);
Single Use Non-Stick Straight Bipolar Forceps, 160mm, 0.5mm Tip with Cable (HNSAG-5160S);
Single Use Non-Stick Straight Bipolar Forceps, 160mm, 1.0mm Tip with Cable (HNSAG-1160S);
Single Use Non-Stick Straight Bipolar Forceps, 180mm, 0.5mm Tip with Cable (HNSAG-5180S);
Single Use Non-Stick Straight Bipolar Forceps, 180mm, 1.0mm Tip with Cable (HNSAG-1180S);
Single Use Non-Stick Straight Bipolar Forceps, 200mm, 1.0mm Tip with Cable (HNSAG-1200S);
Single Use Non-Stick Straight Bipolar Forceps, 200mm, Angled 1.0mm Tip with Cable (HNSAG-1200SA);
Single Use Non-Stick Bayonet Bipolar Forceps, 165mm, 1.0mm Tip with Cable (HNSAG-1165B);
Single Use Non-Stick Bayonet Bipolar Forceps, 200mm, 1.0mm Tip with Cable (HNSAG-1200B);
Single Use Non-Stick Bayonet Bipolar Forceps, 220mm, 1.0mm Tip with Cable (HNSAG-1220B);
Single Use Non-Stick Bayonet Bipolar Forceps, 240mm, 1.0mm Tip with Cable (HNSAG-1240B);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 150mm, 0.5mm Tip with Cable & Irrigation Tubing (HNSAG-5150S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 150mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1150S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 160mm, 0.5mm Tip with Cable & Irrigation Tubing (HNSAG-5160S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 160mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1160S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 180mm, 0.5mm Tip with Cable & Irrigation Tubing (HNSAG-5180S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 180mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1180S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 200mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1200S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 200mm, 2.0mm Tip with Cable & Irrigation Tubing (HNSAG-2200S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 200mm, Angled 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1200SA/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 200mm, Angled 2.0mm Tip with Cable & Irrigation Tubing (HNSAG-2200SA/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 220mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1220S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 220mm, 2.0mm Tip with Cable & Irrigation Tubing (HNSAG-2220S/IRS);

Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 220mm, Angled 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1220SA/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 220mm, Angled 2.0mm Tip with Cable & Irrigation Tubing (HNSAG-2220SA/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 240mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1240S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 240mm, 2.0mm Tip with Cable & Irrigation Tubing (HNSAG-2240S/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 240mm, Angled 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1240SA/IRS);
Single Use Non-Stick, Irrigating, Straight Bipolar Forceps, 240mm, Angled 2.0mm Tip with Cable & Irrigation Tubing (HNSAG-2240SA/IRS);
Single Use Non-Stick, Irrigating, Bayonet Bipolar Forceps, 165mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1165B/IRS);
Single Use Non-Stick, Irrigating, Bayonet Bipolar Forceps, 200mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1200B/IRS);
Single Use Non-Stick, Irrigating, Bayonet Bipolar Forceps, 220mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1220B/IRS);
Single Use Non-Stick, Irrigating, Bayonet Bipolar Forceps, 240mm, 1.0mm Tip with Cable & Irrigation Tubing (HNSAG-1240B/IRS)

Indications for Use *(Describe)*

McPherson 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. 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.

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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: Adeor Medical AG
Predicate Trade Name: Adeor Medical nxt™ Non-stick Bipolar Forceps
Adeor Medical nxt™ Single-Use Non-stick Bipolar Forceps
Predicate 510(k): *K191847*

B) *Predicate 2: Non-irrigating forceps*

Predicate Manufacturer: Faulhaber by Pinzetten OHG
Predicate Trade Name: Single Use Non-Stick Bipolar Forceps sterile/non sterile, Single Use Non-Stick Bipolar Irrigating Forceps sterile/ non sterile
Predicate 510(k): K182773

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The single-use, non-stick bipolar forceps and single-use, non-stick irrigating bipolar forceps (various sizes, designs 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

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. 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.

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

Table 1: Comparison of subject device, Heinrich Single Use Non-Stick Bipolar Forceps with Cable – and Predicate Device, Adeor Medical nxt™ Non-stick Bipolar Forceps Adeor Medical nxt™ Single-Use Non-stick Bipolar Forceps- K191847

Feature	Subject Device	Predicate Device	Justification For Differences
	Heinrich Single Use Non-Stick Bipolar Forceps with Cable – (Multiple models with different sizes)	Adeor Medical nxt™ Non-stick Bipolar Forceps/ Adeor Medical nxt™ Single-Use Non-stick Bipolar Forceps K191847	
Manufacturer	HG Innovations Ltd.	Adeor Medical AG	--------
Regulation	878.4400	878.4400	Same
Classification 21	Class II	Class II	Same
Product Code	GEI	GEI	Same
Device Description	The product family "Single Use Bipolar Forceps", including Heinrich Single Use, Non-Stick Bipolar Forceps (various sizes, designs and tip configurations), with Pre-Attached Cable 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	The Adeor Medical AG Bipolar Forceps are electrosurgical instruments used to grasp, manipulate, cut or coagulate tissue. Bipolar forceps have various lengths and tip configurations, as well as irrigation and suction technologies. Both reusable and single-use forceps are available, with flat plug or two pin plug configurations. Bipolar forceps are connected through a suitable bipolar cable with the bipolar output of a high frequency generator and may be used only with bipolar coagulation current. Adeor bipolar forceps must be operated with the following	Similar

	suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. The Single Use, Non-Stick Bipolar Forceps are single use products and must not be reused.	parameters: Frequency range between 300 kHz and 1,000 kHz: maximum generator operating voltage 600Vp.	
Indications for use	Heinrich Single-use non-stick 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. 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. 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:	The Adeor Medical Non-stick Bipolar Forceps are intended for use by a physician familiar with electrosurgery in bipolar coagulation for general open surgery where coagulation of soft tissue is needed. Adeor bipolar forceps must be operated with the following parameters: Frequency range between 300 kHz and 1,000 kHZ; maximum generator operating voltage 600Vp. The Adeor Medical 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:	Same

	-ENT -Gynecology -Urology -General Surgery -Neurosurgery -Laryngeal Surgery -Orthopedic Surgery -Thoracic Surgery Single-use non-stick bipolar forceps and are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. 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.-Thoracic Surgery	-ENT -Gynecology (except for use in female sterilization) -Urology -General Surgery -Neurosurgery -Laryngeal Surgery -Orthopedic Surgery -Thoracic Surgery	
Rx/ OTC	Rx	Rx	Same
Design	Bayonet	Bayonet	Same
	Mcpherson	N/A	N/A
	Jeweller	N/A	N/A
	Adson	N/A	N/A
	Straight	N/A	N/A
	Irrigating Bayonet	N/A	N/A
	Irrigating Straight	N/A	N/A
Energy Source	Generator	Generator	Same

Single Use	Yes	Both single use and multiuse	Subject device is single use, predicate device has both single use and multiuse devices. Disposable use of subject device reduces risk.
Maximum Peak Voltage	600 Vp	600Vp	Same
Electrode Type	Bipolar	Bipolar	Same
Tip Sizes	0.5mm-1.5mm	0.2mm-1.5mm	Range of tip sizes for predicate device completely overlap that of the subject device. Larger tip will decrease current density and last longer than smaller tips.
Lengths	110mm-240mm	127mm-254mm	Range of lengths is similar and largely overlaps with predicate device.
Component Materials			
Forceps' Tip(s)	Ag800 (80% pure silver)	Ag800 (80% pure silver)	Forceps tip materials are identical for the intended use of the single-use subject device
Arm Material	Stainless steel AISI 420	Stainless Steel	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	Both are made of plastic and are non patient contacting
Colorant	Pigment Blue 15:3 UN8632	N/A	N/A

Forging Blank	Stainless steel AISI 420	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/ Steam	Both are recognized sterility methods.
Shelf-Life Testing	Real-time aging study shows product shelf life up to 3 years	N/A	N/A
Packaging	Paper/Film Pouch Tyvek/Film Pouch	PETG Tray/ Tyvek lid	Similar
Performance Testing			
Biocompatibility (ISO10993-1) *Cytotoxicity (ISO-10993-5)* *Irritation (ISO-10993-10* *Sensitization (ISO-10993-10)* *Pyrogenicity (USP151)* *Systemic Toxicity (ISO-10993-11)*	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)			
High-frequency leakage current	Pass	Pass	Same
High-frequency dielectric strength	Pass	Pass	Same
Mains frequency dielectric strength	Pass	Pass	Same
Active Accessory Insulation	Pass	Pass	Same

Mechanical Testing	Pass	Pass	Same

Table 1: Comparison of subject device, Heinrich Single Use Non-Stick Irrigating Bipolar Forceps with Cable, and Predicate Device, Faulhaber Single Use Non-Stick Bipolar Forceps sterile/non sterile, Single Use Non-Stick Bipolar Irrigating Forceps sterile/ non sterile- K182773

Feature	Subject Device	Predicate Device	Justification For Differences
	Heinrich Single Use Non-Stick Irrigating Bipolar Forceps with Cable (Multiple models with different sizes)	Single Use Non-Stick Bipolar Forceps sterile/non sterile, Single Use Non-Stick Bipolar Irrigating Forceps sterile/ non sterile- K182773	
Manufacturer	HG Innovations Ltd.	Faulhaber by Pinzetten OHG	--------
Regulation	878.4400	878.4400	Same
Classification 21	Class II	Class II	Same
Product Code	GEI	GEI	Same
Device Description	The product family "Single Use Bipolar Forceps", including Heinrich Single Use, Non-Stick Irrigating Bipolar Forceps (various sizes, designs and tip configurations), with Pre-Attached 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,	The product family "Single Use Bipolar Forceps", including Faulhaber Single Use Non-Stick Bipolar Forceps and Single Use Non-Stick Bipolar Irrigating Forceps, are intended to be used for bipolar coagulation and irrigation of tissue by physicians familiar with bipolar coagulation in medical practices and clinics. The Single Use Bipolar Forceps are single use products and must not be reused. They are provided sterile as well as non-sterile.	Similar

	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 Single Use, Non-Stick Bipolar Irrigating Forceps are single use products and must not be reused. The Single Use, Non-Stick Bipolar Irrigating Forceps are with irrigation function. The irrigation function works via a drain running along the forceps tines from tip to handle. At handle height, the drain is connected by Luer-Lock via an irrigation tubing with an irrigation pump.	Products delivered non sterile must be cleaned, disinfected and sterilized before use. For the application the Single Use Bipolar Forceps have to be connected by appropriate bipolar cable to the bipolar output of an HF generator. Bipolar cables and ESU are not part of the subject device. The Single Use Bipolar Forceps are provided in bayonet design with non-stick tips and are identical in design, construction, materials and manufacturing to the reusable device EGON FAULHABER Bipolar Non-Stick Forceps (K101080). The principles of operation and mechanism of action are identical as well. In addition to the cleared and legally marketed EGON FAULHABER devices, the products are with irrigation function available. The irrigation function works via a drain running along the forceps tines from tip to handle. At	

		handle height, the drain is connected by Luer-Lock via an irrigation tubing with an irrigation pump.	
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. 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 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	Faulhaber Single Use Non-Stick Bipolar Forceps sterile/ non-sterile and Single Use Non-Stick Irrigating Forceps sterile/ non-sterile are intended for use by a physician familiar with electrosurgery for bipolar coagulation and irrigation of tissue for general surgery. The bipolar forceps are used with the bipolar output for standard electrosurgical generators. The products are intended for single use and are provided sterile as well as non sterile. Products supplied non sterile must be cleaned, disinfected and sterilized prior to their use by the validated cleaning, disinfection and sterilization process. The bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and	Same

	-Laryngeal Surgery -Orthopedic Surgery -Thoracic Surgery 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 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.	should not be used for these procedures. The types of surgery intended are - General surgery - Laryngeal coagulation - Orthopedic coagulation - Thoracic coagulation - Neurosurgical coagulation - Gynecological coagulation (except for use in female sterilization) - Urological coagulation - Ear-, Nose- and Throat coagulation	
Rx/ OTC	Rx	Rx	Same
Design	Bayonet	Bayonet	Same
	Straight	N/A	N/A
		N/A	N/A
		N/A	N/A
Irrigation feature	Yes	Yes	Same
Energy Source	Generator	Generator	Same
Single Use	Yes	Yes	Same. Disposable use of subject device reduces risk.
Maximum Peak Voltage	600 Vp	<500Vp	Similar
Method of Operation	mechanical activation, no switch	mechanical activation, no switch	

Electrode Type	Bipolar	Bipolar	Same
Tip Sizes	0.5mm-1.5mm	0.5mm-1.5mm	Range of tip sizes for predicate device completely overlap that of the subject device. Larger tip will decrease current density and last longer than smaller tips.
Lengths	150mm-240mm	203mm-300mm	Range of lengths is similar and largely overlaps with predicate device.
Component Materials			
Forceps' Tip(s)	Sterling silver	Sterling Silver	Forceps tip materials are identical for the intended use of the single-use subject device
Arm Material	Coated Stainless steel AISI 420	Coated Stainless Steel	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	Rilsan® (Nylon) Coating	Similar materials used for coating.
Colorant	Pigment Blue 15:3 UN8632	N/A	N/A
Forging Blank	Stainless steel AISI 420	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	N/A	N/A

	107M90T + Master Colour, Black		
Outer Plug Body	Polyvinyl Chloride (PVC)	N/A	Both are made of plastic
Irrigation Pipe	PVC, Silicone	N/A	Both are made of plastic
Irrigation Tube Connection	Female luer located on the forceps near the main housing to be connected with male luer of irrigation tubing	Female luer located on the forceps near the main housing to be connected with male luer of irrigation tubing	Same
Sterility	Sterile	Sterile and non-sterile	Single use, sterile devices pose less risk.
Sterility Testing (ISO-10993-7)	Ethylene Oxide (EO)	Steam Sterilization	Both are recognized sterility methods.
Shelf-Life Testing	Real-time aging study shows product shelf life up to 3 years	N/A	N/A
Packaging	Paper/Film Pouch Tyvek/Film Pouch	*Sterile*: Cleerpeel® Foil Pouch *Non-sterile*: foil bag with cardboard box	Different. Packaging difference does not affect safety of subject device.
Performance Testing			
Biocompatibility (ISO10993-1) *Cytotoxicity (ISO-10993-5) Irritation (ISO-10993-10 Sensitization (ISO-10993-10) Pyrogenicity (USP151) Systemic Toxicity (ISO-10993-11)*	Pass	pass	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)			
High-frequency leakage current	Pass	Pass	Same
High-frequency dielectric strength	Pass	Pass	Same

Mains frequency dielectric strength	Pass	Pass	Same
Active Accessory Insulation	Pass	Pass	Same
Mechanical Testing	Pass	Pass	Same
Drop Test	N/A	Pass	N/A

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.