May 18, 2023

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

Re: K230432
Trade/Device Name: Single Use Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 17, 2023
Received: February 17, 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 (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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.18 11:13:23 -04'00'

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
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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.

510(k) Number *(if known)*
K230432

Device Name
Single Use Bipolar Forceps

Indications for Use *(Describe)*
Single-use, bipolar forceps are intended for bipolar coagulation to remove tissue and control bleeding by use of high frequency electrical current.

The bipolar forceps must be operated with the following parameters:
-Frequency range between 300 kHz-1,000 kHZ;
-Maximum generator operating voltage 600Vp.

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- K230432

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

I. SUBMITTER:

HG Innovations Ltd.
5 Elder Court,
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Blackburn Lancashire, BB1 2EQ UK

Contact Person: Dr. M. Umran Rafiq
Phone No: +44 7702195623

Date Prepared: May 17, 2023

II. DEVICE

Device Trade Name: Single Use 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

Predicate Manufacturer: Titan Manufacturing Inc.
Predicate Trade Name: Titan Manufacturing Bipolar Forceps
Predicate 510(k): K213386

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, bipolar forceps (various lengths and designs), with preattached cables are designed to grasp, manipulate and 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 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, bipolar forceps are intended for bipolar coagulation to remove tissue and control bleeding by use of high frequency electrical current.

The bipolar forceps must be operated with the following parameters:
-Frequency range between 300 kHz-1,000 kHZ;
-Maximum generator operating voltage 600Vp.

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

Feature	Subject Device	Predicate Device	Justification For Differences
	Single-use Bipolar Forceps with cable (Multiple models with different designs and sizes)	Titan Manufacturing Bipolar Forceps – *K213386* (Multiple models with different designs and sizes)	
Manufacturer	HG Innovations Ltd.	Titan Manufacturing, Inc.	--------
Regulation	878.4400	878.4400	Same
Classification 21	Class II	Class II	Same
Product Code	GEI	GEI	Same
Electrode Type	Bipolar	Bipolar	Same
Cable included	Yes	No	Different
Principles of Operation	The blood vessel or tissue is grasped between the forceps tines or tips, 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.	Bipolar forceps are designed to grasp, manipulate, and coagulate selected tissue. They are to be connected through a bipolar cable with the bipolar output of an electrosurgical generator. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit (ESU) and activated by a footswitch. Bipolar cables, ESU and footswitch are not part of the subject device.	The wording for principles of operation are different, but the principles of operation are equivalent.
Indications for use	Single-use, bipolar forceps are intended for bipolar coagulation to remove tissue and control bleeding by use of high frequency	Titan Manufacturing Bipolar Forceps are intended to remove tissue and control bleeding by use of	Subject device includes “bipolar coagulation” which is how bleeding is controlled. The

	electrical current. The bipolar forceps must be operated with the following parameters: -Frequency range between 300 kHz-1,000 kHZ; -Maximum generator operating voltage 600Vp.	high frequency electrical current.	operating parameters were also added to the indications of the subject device.
Rx/ OTC	Rx	Rx	Same
Design	Straight	Straight	Same
	Jeweler	N/A	Similar to predicate (materials, components)
	Angled	Angled	Same
	Adson	N/A	Similar to predicate (materials, components)
	McPherson	N/A	Similar to predicate (materials, components)
	McPherson, Angled	N/A	Similar to predicate (materials, components)
	Bayonet	N/A	Similar to predicate (materials, components)
	N/A	Curved	N/A
	N/A	Coaptation	N/A
	Insulated	Insulated/ noninsulated	Same
	N/A	Insulating/ Irrigating	N/A
	N/A	Non-insulating/ Irrigating	N/A
Energy Source	Generator	Generator	Same
Single Use	Yes	Reusable	Disposable use of subject device eliminates risk of reuse.
Tip Sizes	0.5-2mm	0.2mm-2mm	Range of tip sizes falls within range of predicate device.
Lengths	102-240mm	89mm-273mm	Range of lengths falls within range of predicate device.
Component Materials			
Forceps' Tip(s)	Stainless Steel AISI 420	Stainless Steel or titanium	Subject device is equivalent to the stainless steel

			model of the predicate.
Arm Material	Stainless Steel AISI 420	Stainless Steel or titanium	Subject device is equivalent to the stainless steel model of the predicate.
Adhesive	None	Epoxy	N/A. Subject device legs are over-molded to foot instead of using adhesives.
Outer Cap	Polypropylene, SABIC® PP 107M90T + Master Color, Black	N/A	Used for shipping purposes only, because subject device is shipped sterile.
Cable	Polyvinyl Chloride (PVC), 2/16 core, Copper Wires	Not included	Cable wires used in subject device is made of equivalent materials to predicate wires.
Solder	Tin	N/A	N/A
Powder Coating	Polyamide 11	Polyvinylidene Fluoride (PVDF)	Equivalent, both are thermoplastics.
Colorant	Pigment Blue 15:3 UN8632	Kynar (blue)	Both colorants are non-patient contacting.
Forging Blank	Stainless Steel AISI 420	N/A	N/A
Inner Cap	Polypropylene, SABIC® PP 107M90T + Master Color, 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 Color, Black	N/A	N/A
Outer Plug Body	Polyvinyl Chloride (PVC)	N/A	Both are made of plastic
Sterilization Method & SAL	Ethylene Oxide (EO), provided sterile to user **SAL= 10^{-6}**	Provided non-sterile to user for pre-vacuum sterilization (steam). **SAL= 10^{-6}**	Equivalent. Both meet requirement for sterile products.

Shelf-Life Testing	Real-time aging study shows product shelf life up to 3 years	N/A	N/A
Packaging	Paper/film (Tyvek/Film) pouch	Bipolar forcep in a propionate clear hard plastic tube with foam insets at both ends packaged in an instrument sturdy box with packaging material to protect the instrument (bipolar forcep)	Equivalent. Both meet requirements for package integrity.
Performance Testing			
Biocompatibility (ISO 10993-1)			
Cytotoxicity (ISO 10993-5)	Non-Cytotoxic	Non-Cytotoxic	Same
Irritation (ISO 10993-23)	Non-Irritating	Non-Irritating	Same
Sensitization (ISO 10993-10)	Non-Sensitizing	Non-Sensitizing	Same
Pyrogenicity (USP151)	<10 EU/ sample (Pass)	Pass	Same
Systemic Toxicity (ISO 10993-11)	Non-Toxic	Non-Toxic	Same
Selection of Tests for Interactions with Blood (ISO 10993-4)	N/A	Pass	Not required for intended use.
Electrical Safety IEC-60601-2-2			
HiPot & Continuity Test Dielectric strength insulation; insulated safety plug;	Pass	Pass	Same
Compatible with general electrosurgical generators with 4mm outlets	Pass	Pass	Same
Drop Test	Pass	Pass	Same

VII. CONCLUSION

HG Innovation's bipolar forceps are identical to the predicate device in their intended use/indications for use and construction material of the tips. The tip-size range of the subject device also completely overlaps with that of the predicate device. There is a difference in the specific arm/body coatings used between the subject device and the predicate device.

Based on the indications for use, comparison of technological characteristics with the predicate device, and results of performance testing, the subject device is substantially equivalent to the predicate for the proposed indications for use.