October 25, 2021

Titan Manufacturing, Inc.
℅ Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive
Suite #510k
Saint Paul, Minnesota 55114

Re: K213386
Trade/Device Name: Titan Manufacturing 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: October 12, 2021
Received: October 13, 2021

Dear Prithul Bom:

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

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)*
K213386

Device Name
Titan Manufacturing Bipolar Forceps

Indications for Use *(Describe)*
Titan Manufacturing Bipolar Forceps are intended to remove tissue and control bleeding by use of high frequency electrical current.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Titan Manufacturing Inc.

1 Rapps Run Drive
Malvern, PA 19355

Ph: (610) 935-8203
Fx: (610) 933-9771
www.titanmfg.com

K213386

510(k) Summary

Device Name: Titan Manufacturing Bipolar Forceps

Submission Sponsor:	Titan Manufacturing, Inc.	
Contact Person:	Donald Seavey, President	
Address/Phone#/Email:	Owner Operator: 1 Rapps Run Malvern, PA 19355 610-935-8203 don@titanmfg.com	Manufacturing Site: 818 Jefferson St Fall River, MA 02721 610-935-8203 don@titanmfg.com
Owner Operator/Manufacturing Site Establishment Registration #s:	9025545	3001452522

Submission Correspondent:	WolfKat Regulatory Consulting, LLC.
Contact Person:	Katrina Fiedler, Founder & Principal Consultant
Address/Phone#/Email:	44 Oxford Drive East Windsor, NJ 08520 609-902-6162 katrina@wolfkatreg.com

Date of Preparation:	October 22, 2021 [REVISED]

Type of Submission:	Traditional 510(k) Premarket Notification

Device Identification	
Trade/Proprietary Name:	Titan Manufacturing Bipolar Forceps
Common Name:	Bipolar Forceps
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	§878.4400
Product Code:	GEI
Review Panel:	General & Plastic Surgery

Predicate Devices 510(k) #	**Product Name**	**Manufacturer**
K974593	Semkin Insulated Bipolar Forcep	Titan Manufacturing, Inc.
K974594	Semkin Bipolar Forcep	Titan Manufacturing, Inc.
K974595	Cushing Bayonet Insulated Bipolar Forcep	Titan Manufacturing, Inc.

These predicates have not been subject to a design-related recall.

Titan Manufacturing Inc.

1 Rapps Run Drive
Malvern, PA 19355

Ph: (610) 935-8203
Fx: (610) 933-9771
www.titanmfg.com

K213386

Reference Device 510(k) #	Product Name	Manufacturer
K121426	Synergetics Disposable Spetzler Malis Standard Bipolar Forceps	Synergetics
K182773	Faulhaber Pinzetten OHG Single-Use Non-Stick Bipolar Forceps sterile/non-sterile; Faulhaber Pinzetten OHG Single-Use Bipolar Irrigating forceps sterile/non-sterile	Faulhaber Pinzetten OHG

Indications For Use

Titan Manufacturing Bipolar Forceps are intended to remove tissue and control bleeding by use of high frequency electrical current.

Device Description

Titan Manufacturing Bipolar Forcep is a generic electrosurgical device (handpiece)/active accessory that is to be connected through a bipolar cable with the bipolar output of a standard, general electrosurgical generator unit (ESU) and footswitch. The bipolar cable, ESU and footswitch are not part of the subject device, therefore not included in this submission. The subject device is not an electrosurgical vessel sealer system.

Titan Manufacturing Bipolar Forceps are indicated for use in general surgical procedures; designed to grasp, manipulate, and coagulate selected tissue.

Titan Manufacturing Bipolar Forceps are to be connected through a suitable bipolar cable [not supplied by Titan Manufacturing, Inc.] with the bipolar output of a standard, general electrosurgical generator [not supplied by Titan Manufacturing, Inc.]. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch [not supplied by Titan Manufacturing, Inc.].

Titan Manufacturing, Inc., offers an extensive line of precision crafted reusable stainless steel and titanium bipolar forceps in a multitude of handle styles, lengths, and tip sizes. Titan Manufacturing Bipolar Forceps are available in styles such as but not limited to straight and bayonet styles, patterned designs such as but not limited to Semkin, Jewelers, Adson, Scoville-Greenwood, Ti Square Grip, Yargasil, Tenzel, McPherson, and Cozean, etc. Titan Manufacturing offers bipolar forceps in lengths from approximately 3 ½ inches to 10 ¾ inches.; titanium or stainless steel; insulated or non-insulated; irrigating or non-irrigating; straight, curved, angled or coaptation; and varying tip sizes from 0.2mm to 2.0mm. The product line is similar to those offered by other well-established bipolar forcep manufacturers [e.g., Codman, Kirwin, Faulhaber Pinzetten, Synergetics (a.k.a. Stryker), etc.].

Titan Manufacturing Bipolar Forceps are reusable medical devices, provided non-sterile and must be cleaned and sterilized prior to use. They are used with the bipolar output for standard, general electrosurgical generators (ESU). The Titan Manufacturing Bipolar Forceps are compatible with

1 Rapps Run Drive
Malvern, PA 19355

Ph: (610) 935-8203
Fx: (610) 933-9771
www.titanmfg.com

general electrosurgical generators with 4mm outlets; U.S. 2-pin plugs. Bipolar cables, ESU and footswitch are not part of the subject device.

Titan Manufacturing Bipolar Forceps are available in four (4) general model types in stainless steel or titanium: Non-insulated; Insulated; Non-insulated/Irrigating; and Insulated/Irrigating.

Substantial Equivalence Discussion
Comparison [Subject Device vs. Predicate Devices]

	Subject Device	**Predicate Device**	**Predicate Device**	**Predicate Device**	**Same or Different**
510(k) Number	K213386	K974593	K974594	K974595	----------------
Product Name	Titan Manufacturing Bipolar Forceps	Semkin Insulated Bipolar Forcep	Semkin Bipolar Forcep	Cushing Bayonet, Insulated Bipolar Forcep	----------------
Manufacturer	Titan Manufacturing, Inc.	Titan Manufacturing, Inc.	Titan Manufacturing, Inc.	Titan Manufacturing, Inc.	SAME
Classification	Class II	Class II	Class II	Class II	SAME
Subsequent Product Code	GEI	GEI	GEI	GEI	SAME
Regulation	878.4400	878.4400	878.4400	878.4400	SAME
Rx or OTC	Rx	Rx	Rx	Rx	SAME
Intended Use	Titan Manufacturing Bipolar Forceps are intended to remove tissue and control bleeding by use of high frequency electrical current.	Semkin Insulated Bipolar Forceps are intended to remove tissue and control bleeding by use of high frequency electrical current.	Semkin Bipolar Forceps are intended to remove tissue and control bleeding by use of high frequency electrical current.	Cushing Bayonet, Insulated Bipolar Forceps are intended to remove tissue and control bleeding by use of high frequency electrical current.	SAME
Principles of Operation	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.	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.	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.	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.	SAME
Electrode Type	Bipolar	Bipolar	Bipolar	Bipolar	SAME
Physical Dimensions Available	3 ½ inches to 10 ¾ inches in length	3 ½ inches to 10 ¾ inches in length	3 ½ inches to 10 ¾ inches in length	3 ½ inches to 10 ¾ inches in length	SAME
Tip Sizes Available	0.2mm to 2.0mm	0.2mm to 2.0mm	0.2mm to 2.0mm	0.2mm to 2.0mm	SAME

Titan
Manufacturing Inc.

1 Rapps Run Drive
Malvern, PA 19355

Ph: (610) 935-8203
Fx: (610) 933-9771
www.titanmfg.com

K213386

Substantial Equivalence Discussion
Comparison [Subject Device vs. Predicate Devices]
(cont'd)

	Subject Device	**Predicate Device**	**Predicate Device**	**Predicate Device**	**Same or Different**
Materials	Stainless Steel or Titanium Epoxy Kynar Insulation Coating [Polyvinylidene Fluoride (PVDF)]	Stainless Steel or Titanium Epoxy Kynar Insulation Coating [Polyvinylidene Fluoride (PVDF)]	Stainless Steel or Titanium Epoxy Kynar Insulation Coating [Polyvinylidene Fluoride (PVDF)]	Stainless Steel or Titanium Epoxy Kynar Insulation Coating [Polyvinylidene Fluoride (PVDF)]	SIMILAR; Source Supplier for Kynar different for subject device.
Visual Appearance Insulated Bipolar Forceps	Lighter, semi-gloss, blue-colored insulating coating material	Dark, matte, blue-colored insulating coating material	Dark, matte, blue-colored insulating coating material	Dark, matte, blue-colored insulating coating material	SIMILAR – blue colorant, Kynar
Sterilization Recommendations	Pre-Vacuum Steam	Pre-Vacuum Steam	Pre-Vacuum Steam	Pre-Vacuum Steam	SAME
Re-usable	YES	YES	YES	YES	SAME
Packaging	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)	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)	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)	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)	SAME
Biocompatible	YES	YES	YES	YES	SAME
Drop Test	YES	YES	YES	YES	SAME
Cable Connector Type	Compatible with U.S. 2-pin round plugs	Compatible with U.S. 2-pin round plugs	Compatible with U.S. 2-pin round plugs	Compatible with U.S. 2-pin round plugs	SAME
Electrical Safety Features	HiPot & Continuity Test Dielectric strength insulation; insulated safety plug; Compatible with general electrosurgical generators with 4mm outlets	HiPot & Continuity Test Dielectric strength insulation; insulated safety plug; Compatible with general electrosurgical generators with 4mm outlets	HiPot & Continuity Test Dielectric strength insulation; insulated safety plug; Compatible with general electrosurgical generators with 4mm outlets	HiPot & Continuity Test Dielectric strength insulation; insulated safety plug; Compatible with general electrosurgical generators with 4mm outlets	SAME

Titan Manufacturing Inc.

1 Rapps Run Drive
Malvern, PA 19355

Ph: (610) 935-8203
Fx: (610) 933-9771
www.titanmfg.com

K213386

Comparison [Subject Device vs. Reference Devices]

	Subject Device	**Reference Device #1**	**Reference Device #2**	**Same or Different**
510(k) Number	K213386	K121426	K182773	----------
Product Name	Titan Manufacturing Bipolar Forceps	Synergetics Disposable Spetzler Malis Standard Bipolar Forceps	Faulhaber Pinzetten OHG Single-Use Non-Stick Bipolar Forceps sterile/non-sterile; Faulhaber Pinzetten OHG Single-Use Bipolar Irrigating forceps sterile/non-sterile	----------
Manufacturer	Titan Manufacturing, Inc.	Synergetics	Faulhaber Pinzetten OHG	----------
Classification	Class II	Class II	Class II	SAME
Product Code	GEI	GEI	GEI	SAME
Regulation	878.4400	878.4400	878.4400	SAME
Rx or OTC	Rx	Rx	Rx	SAME
Intended Use	Titan Manufacturing Bipolar Forceps are intended to remove tissue and control bleeding by use of high frequency electrical current.	The Synergetics Disposable Spetzler-Malis Standard Bipolar Forceps are single use device sold sterile and are intended for use in electrosurgery for coagulation of tissue.	Faulhaber Single Use Non-Stick Bipolar Forceps sterile/non-sterile and Single-Use Non-Stick Bipolar 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 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 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 sterilization) -Urological coagulation -Ear, Noe, Throat coagulation.	SIMILAR – Intended use for subject device is general; Subject device is reusable and provided non-sterile.

Titan
Manufacturing Inc.

1 Rapps Run Drive
Malvern, PA 19355

Ph: (610) 935-8203
Fx: (610) 933-9771
www.titanmfg.com

K213386

Comparison [Subject Device vs. Reference Devices] (cont'd)

	Subject Device	**Reference Device #1**	**Reference Device #2**	**Same or Different**
Principles of Operation	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.	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 required for operation, but not provided.	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 required for operation, but not provided.	SAME
Electrode Type	Bipolar	Bipolar	Bipolar	SAME
Materials	Stainless Steel or Titanium Epoxy Kynar® Insulation Coating [Polyvinylidene Fluoride PVDF)]	Stainless Steel or Titanium Epoxy Insulation Coating [Polyvinylidene Fluoride (PVDF)]	Stainless Steel Epoxy Insulation Coating [Rilsan (Nylon)]	SIMILAR – Brand of PVDF not known for 1st cited reference device; Similar insulation coating material for 2nd cited reference device
Biocompatible	YES	YES	YES	SAME
Cable Connector Type	Compatible with U.S. 2-pin round plugs	Compatible with U.S. 2-pin round plugs	Compatible with U.S. 2-pin round plugs	SAME
Safety Features	Dielectric strength insulated safety plug	Dielectric strength insulated safety plug	Dielectric strength insulated safety plug	SAME

1 Rapps Run Drive
Malvern, PA 19355

Ph: (610) 935-8203
Fx: (610) 933-9771
www.titanmfg.com

Non -Clinical Performance Testing

Nonclinical testing has been conducted to verify that the Titan Manufacturing Bipolar Forceps met all design specifications and are substantially equivalent to the predicate devices. Testing included the following:

- Biocompatibility Testing performed in accordance with the following:
  - ISO 10993-5:2009 "Biological Evaluation of Medical Devices – Part 5: *In Vitro* Cytotoxicity Test"
  - ISO 10993-10:2010 "Biological Evaluation of Medical Devices – Part 10: Skin Sensitization Test"
  - ISO 10993-10:2010 "Biological Evaluation of Medical Devices – Part 10: Skin Intracutaneous Reactivity Test"
  - USP 151 Material Mediated Pyrogenicity – Rabbit Pyrogen Test
  - ISO 10993-11: "Biological Evaluation of Medical Devices – Part 11: Tests for Acute Systemic Toxicity"
  - ISO 10993-4:2017 "Biological Evaluation of Medical Devices – Part 4, Selection of Tests for Interactions with Blood"
- Medical Electrical Equipment Safety Testing performed in accordance with the following:
  - IEC 60601-2-2 Ed. 6 (2017)
- Cleaning and Sterilization Recommendations IFU Validation

In addition, Titan Manufacturing Bipolar Forceps have been compared to the predicate device through various performance studies designed to test visual/operational use, performance and electrical safety and effectiveness.

The testing results demonstrated the Titan Manufacturing Bipolar Forceps performed equivalent to the predicate devices.

- Current vs. New Kynar Equivalency Tests [Validation – Change in Kynar Insulation Coating Material Supplier]:
  - Sprayability;
  - Durability (Stress) Drop;
  - Finish/Appearance;
  - Heat;
  - Hipot; and
  - Continuity.

The testing results demonstrated the Titan Manufacturing Bipolar Forceps performed equivalent to the predicate devices.

Electrical performance of the device was completed following FDA Guidance "Premarket Notification [510(k) Submissions for Electrosurgical Devices for General Surgery", issued August 15, 2016. This required (thermal spread) testing on three (3) different tissue types at minimum, default, and maximum

1 Rapps Run Drive
Malvern, PA 19355

Ph: (610) 935-8203
Fx: (610) 933-9771
www.titanmfg.com

generator power to simulate thermal spread across different tissue types. The spread was then measured and recorded, compared to predicate devices. Results demonstrated an equivalent thermal spread under the same conditions across the different tissue types and power settings.

Clinical Performance Testing

There were no clinical trials performed on these devices.

Statement of Substantial Equivalence

The subject device has the same intended use and technological characteristics as the cited predicate devices. The minor changes or differences presented do not affect the safety or performance of the subject device or raise new questions of safety or effectiveness. The non-clinical test results have demonstrated the subject device is as safe as the predicate devices.

Therefore, it is concluded that no new questions of safety and effectiveness were raised.
We conclude that the subject device is substantially equivalent to the cited predicate devices.