March 17, 2022

Modern Medical Equipment Manufacturing, LTD.
Mr. Philip Hung
QA Manager / Management Representative
Unit A, 10/F., Mai Wah Ind. Bldg.,
1-7 Wah Sing Street,
Kwai Chung, N.T., Hong Kong,
China

Re: K210315
Trade/Device Name: Monopolar and Bipolar Forceps (with and without Smoke Evacuation).
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI

Dated: January 04, 2022
Received: January 26, 2022

Dear Mr. Hung:

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)*
K210315

Device Name
Monopolar and Bipolar Forceps (with and without Smoke Evacuation)

Indications for Use *(Describe)*

1. Single Use Hand Switch Monopolar Forceps with Smoke Evacuation (CD954)
The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery.

2. Single Use Hand Switch Bipolar Forceps with Smoke Evacuation (CD955)
The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery.

3. Single Use Hand Switch Monopolar Forceps (CD956)
The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure.

4. Single Use Hand Switch Bipolar Forceps (CD957)
The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure.

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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1. 510(k) Owner

Name: Modern Medical Equipment Manufacturing Limited

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Contact person: Mr. Philip Hung

Position: Quality Assurance Manager / Management Representative

Email Address: philip_hung@modernmedical.com.hk

Date of preparation: Feb14, 2022

2. Device

Device Trade name: Monopolar and Bipolar Forceps
(with and without Smoke Evacuation)

Common or usual name: Single Use Hand Switch Monopolar and Bipolar Forceps;
Single Use Hand Switch Monopolar and Bipolar Forceps with Smoke Evacuation.

Classification name: Electrosurgical Cutting & Coagulation Device & Accessories

Classification number: 21 CFR 878.4400

Classification Panel: General & Plastic Surgery

Product Code: GEI

Class: II

3. Predicate device

3.1 Olsen Medical SINGLE USE & MULTI USE BIPOLAR FORCEPS / SINGLE USE & MULTI USE
MONOPOLAR FORCEPS with 510(k) number K130669, cleared Dec 06,2013.

3.2 Modern Medical Smoke Evacuation Fingerswitch, Smoke Evacuation System With Electrosurgical
Pencil with 510(k) number K200372, cleared Nov 30, 2020.

3.3 Modern Medical Bipolar Forceps with 510(k) number K032327

4. Device description

Modern Medical Electrosurgical Monopolar Forceps and Bipolar Forceps have been designed as active electrosurgical instruments to grasp, manipulate coagulate selected soft tissue. These stainless steel forceps are connected through a suitable active electrosurgical cable (monopolar or bipolar) to the specified output terminal of an electrosurgical generator. The forceps are intended for use with rated accessory voltage of 2.0kVp. The forceps are offered sterile (EtO) and either as with or without smoke evacuation system which include four models, such as CD954, CD955, CD956 and CD957. Please refer it to the item 6, **<Indication for use>** for the detail of these four models.

5. Intended use

The device is intended to be used as active electrosurgical devices where monopolar or bipolar electrosurgical coagulation is desired during surgery and are intended to grasp, manipulate coagulate selected soft tissue.

6. Indication for use

6.1 Single Use Hand Switch Monopolar Forceps with Smoke Evacuation (CD954)

The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery

6.2 Single Use Hand Switch Bipolar Forceps with Smoke Evacuation (CD955)

The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery.

6.3 Single Use Hand Switch Monopolar Forceps (CD956)

The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure.

6.4 Single Use Hand Switch Bipolar Forceps (CD957)

The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure.

7. Technological characteristics

Single Use Hand Switch Forceps has substantially equivalent construction and performance as the predicate devices.

8. Substantial Equivalence

The technological characteristics and performance testing of the subject and predicate devices are substantially equivalent.

1. **Table 1: Subject-Predicate Comparison**
   Proposed device: Single Use Hand Switch Monopolar Forceps with Smoke Evacuation_(CD954)
   Predicate device: K130669 and K200372

Compared Items	Proposed Device （K210315） Single Use Hand Switch Monopolar Forceps with Smoke Evacuation	Predicate Device (K130669) Olsen Medical Bipolar and Monopolar Forceps	Predicate Device (K200372) Single Use Smoke Evacuation Fingerswitch / Pencil	Result	Comments on difference/ equivalent evidence
Classification Name	Electrosurgical, Cutting and Coagulation Accessories	Electrosurgical, Cutting and Coagulation Accessories	Electrosurgical, Cutting and Coagulation Accessories	Equivalent	
Regulation	878.4400	878.4400	878.4400	Equivalent	
Common Name	Single Use Hand Switch Monopolar Forceps with Smoke Evacuation	Single Use Bipolar and Monopolar Forceps Multiple-Use Bipolar and Monopolar Forceps	Single Use Smoke Evacuation Fingerswitch / Pencil	Equivalent	
Product Code	GEI	GEI	GEI	Equivalent	

Intended use	The device is intended to be used as active electrosurgical devices where monopolar electrosurgical coagulation is desired during surgery and are intended to grasp, manipulate coagulate selected soft tissue.	The OLSEN Medical Electrosurgical Monopolar and Bipolar Forceps are intended to be used as active electrosurgical devices where monopolar or bipolar electrosurgical cutting and coagulation is desired during surgery and are intended to grasp, manipulate cut or coagulate selected soft tissue.	Monopolar cutting and coagulation in electrosurgical procedure, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery.	Equivalent	Evidence: IFU
Prescription or OTC	Prescription Use	Prescription Use	Prescription Use	Equivalent	
Indication for use	The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery.	OLSENMedical® Electrosurgical Monopolar and Bipolar Forceps have been designed as active electrosurgical instruments to grasp, manipulate, cut or coagulate selected soft tissue. These stainless steel forceps are connected through a suitable active electrosurgical cable (bipolar or monopolar) to the specified	Monopolar electrosurgical pencil which delivers electrosurgical current to target tissue for cutting and coagulation in electrosurgical procedure, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery.	Equivalent	Evidence: IFU

		output terminal of an electrosurgical generator.			
Sterility	ETO	Irradiation	ETO	Equivalent	ETO sterilization validation have done for this device. Evidence: EO validation report number R-EO2011
Usage	Single Use	Disposable and reusable	Single Use	Equivalent	Evidence: IFU
Tip Material	Stainless Steel	Stainless Steel	Stainless Steel	Equivalent	Evidence: Material Technical Data Sheet
Size (distal tips)	0.1-1.2mm	0.5-1.5mm	0.5mm	Not Equivalent	Tip Size doesn't increase any risk for the product. Evidence: Simulation test report 956MVPE1N-2111123R.
Packaging	Tyvek Pouch	Tyvek Pouch	Tyvek Pouch	Equivalent	Evidence: IFU
Electrical Safety Testing	IEC 60601-2-2	IEC 60601-2-2	IEC 60601-2-2	Equivalent	Evidence: DSS_GZES200802563702-IEC 60601-2-2
Energy delivery	Monopolar electrosurgical Forceps which delivers electrosurgical current to target tissue.	Monopolar or bipolar electrosurgical Forceps which delivers electrosurgical current to target tissue.	Monopolar electrosurgical Forceps which delivers electrosurgical current to target tissue.	Equivalent	Evidence: test report number 954MVPE2N-2012196R
Rated Accessory Voltage	2.0kVp	The bipolar forceps are intended for use with a maximum voltage of 500 volts while the monopolar forceps have a	4.5kVp	Equivalent	Evidence: Accelerated aging test report

		maximum voltage of 2000 volts.			
Biocompatibility	Non irritant, non sensitive to skin, non toxic to cells	Non irritant, non sensitive to skin, non toxic to cells	Non irritant, non sensitive to skin, non toxic to cells	Equivalent	Evidence: Biocompatibility test report
Shelf life	3 years	3 years	3 years	Equivalent	Evidence: Labeling
Target population	All patients, no specific restriction	All patients, no specific restriction	All patients, no specific restriction	Equivalent	Evidence: IFU
Where used	Hospitals	Hospitals	Hospitals	Equivalent	Evidence: IFU

Table 2: Subject-Predicate Comparison
Proposed device: Single Use Hand Switch Bipolar Forceps with Smoke Evacuation_(CD955)
Predicate device: K032327

Compared Items	Proposed Device （K210315） Single Use Hand Switch Bipolar Forceps with Smoke Evacuation	Predicate Device (K032327) Modern Medical Bipolar Forceps	Result	Comments on difference/ equivalent evidence
Classification Name	Electrosurgical, Cutting and Coagulation Accessories	Electrosurgical, Cutting and Coagulation Accessories	Equivalent	
Regulation	878.4400	878.4400	Equivalent	
Common Name	Single Use Hand Switch Bipolar Forceps with Smoke Evacuation	Modern Medical Bipolar Forceps	Equivalent	
Product Code	GEI	GEI	Equivalent	

Intended use	The device is intended to be used as active electrosurgical devices where bipolar electrosurgical coagulation is desired during surgery and are intended to grasp, manipulate r coagulate selected soft tissue.	The device is intended to be used as active electrosurgical devices where bipolar electrosurgical coagulation is desired during surgery and are intended to grasp, manipulate r coagulate selected soft tissue.	Equivalent	Evidence: IFU
Prescription or OTC	Prescription Use	Prescription Use	Equivalent	
Indication for use	The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery.	The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery.	Equivalent	Evidence: IFU
Sterility	ETO	Irradiation	Equivalent	ETO sterilization validation have done for this device. Evidence: EO validation report number R-EO2011
Usage	Single Use	Disposable and reusable	Equivalent	Evidence: IFU
Tip Material	Stainless Steel	Stainless Steel	Equivalent	Evidence: Material Technical Data Sheet
Size (distal tips)	0.1-1.2mm	0.5-2.0mm	Not equivalent	Tip Size doesn't increase any risk for the product. Evidence:

				955MVPE1N-2111122R.
Packaging	Tyvek Pouch	Tyvek Pouch	Equivalent	Evidence: IFU
Electrical Safety Testing	IEC 60601-2-2	IEC 60601-2-2	Equivalent	Evidence: DSS_GZES200802563702-IEC 60601-2-2
Energy delivery	Bipolar electrosurgical Forceps which delivers electrosurgical current to target tissue.	Monopolar or bipolar electrosurgical Forceps which delivers electrosurgical current to target tissue.	Equivalent	Evidence: test report number 954MVPE2N-2012196R
Rated Accessory Voltage	2.0kVp	The bipolar forceps are intended for use with a maximum voltage of 500 volts while the monopolar forceps have a maximum voltage of 2000 volts.	Equivalent	Evidence: Accelerated aging test report
Biocompatibility	Non irritant, non sensitive to skin, non toxic to cells	Non irritant, non sensitive to skin, non toxic to cells	Equivalent	Evidence: Biocompatibility test report
Shelf life	3 years	3 years	Equivalent	Evidence: Labeling
Target population	All patients, no specific restriction	All patients, no specific restriction	Equivalent	Evidence: IFU
Where used	Hospitals	Hospitals	Equivalent	Evidence: IFU
Functionality	With smoke evacuation	Without smoke evacuation	Not equivalent	The smoke evacuation is a features that be added to the forceps to increase convenience of functionality, without altering the intended use or risk profile (relative to a predicate) of the proposed device. Instead, smoke evacuation functionality.

				Evidence: Simulation test report. 955MVPE1N-2111121R

Table 3: Subject-Predicate Comparison
Proposed device: Single Use Hand Switch Monopolar Forceps _(CD956)
Predicate device: K130669

Compared Items	Proposed Device (K210315) Single Use Hand Switch Monopolar Forceps	Predicate Device (K130669) Olsen Medical Bipolar and Monopolar Forceps	Result	Comments on difference/ equivalent evidence
Classification Name	Electrosurgical, Cutting and Coagulation Accessories	Electrosurgical, Cutting and Coagulation Accessories	Equivalent	
Regulation	878.4400	878.4400	Equivalent	
Common Name	Single Use Hand Switch Monopolar Forceps	Single Use Bipolar and Monopolar Forceps Multiple-Use Bipolar and Monopolar Forceps	Equivalent	
Product Code	GEI	GEI	Equivalent	
Intended use	The device is intended to be used as active electrosurgical devices where monopolar electrosurgical coagulation is desired during surgery and are intended to grasp, manipulate coagulate selected soft tissue.	The OLSEN Medical Electrosurgical Monopolar and Bipolar Forceps are intended to be used as active electrosurgical devices where monopolar or bipolar electrosurgical cutting and coagulation is desired during surgery and are intended to grasp, manipulate cut or coagulate selected soft tissue.	Equivalent	Evidence: IFU
Prescription or OTC	Prescription Use	Prescription Use	Equivalent	

Indication for use	The device delivers electrosurgical current to target tissue for and coagulation in electrosurgical procedure.	OLSENMedical® Electrosurgical Monopolar and Bipolar Forceps have been designed as active electrosurgical instruments to grasp, manipulate, cut or coagulate selected soft tissue. These stainless steel forceps are connected through a suitable active electrosurgical cable (bipolar or monopolar) to the specified output terminal of an electrosurgical generator.	Equivalent	Evidence: IFU
Sterility	ETO	Irradiation	Equivalent	ETO sterilization validation have done for this device. Evidence: EO validation report number R-EO2011
Usage	Single Use	Disposable and reusable	Equivalent	Evidence: IFU
Tip Material	Stainless Steel	Stainless Steel	Equivalent	Evidence: Material Technical Data Sheet
Size (distal tips)	0.1-1.2mm	0.5-1.5mm	Not Equivalent	Tip Size doesn't increase any risk for the product. Evidence: Simulation test report 956MVPE1N-2111123R.
Packaging	Tyvek Pouch	Tyvek Pouch	Equivalent	Evidence: IFU
Electrical Safety Testing	IEC 60601-2-2	IEC 60601-2-2	Equivalent	Evidence: DSS_GZES200802563702-IEC 60601-2-2

Energy delivery	Monopolar electrosurgical Forceps which delivers electrosurgical current to target tissue.	Monopolar or bipolar electrosurgical Forceps which delivers electrosurgical current to target tissue.	Equivalent	Evidence: test report number 954MVPE2N-2012196R
Rated Accessory Voltage	2.0kVp	The bipolar forceps are intended for use with a maximum voltage of 500 volts while the monopolar forceps have a maximum voltage of 2000 volts.	Equivalent	Evidence: Accelerated aging test report
Biocompatibility	Non irritant, non sensitive to skin, non toxic to cells	Non irritant, non sensitive to skin, non toxic to cells	Equivalent	Evidence: Biocompatibility test report
Shelf life	3 years	3 years	Equivalent	Evidence: Labeling
Target population	All patients, no specific restriction	All patients, no specific restriction	Equivalent	Evidence: IFU
Where used	Hospitals	Hospitals	Equivalent	Evidence: IFU

Table 4: Subject-Predicate Comparison
Proposed device: Single Use Hand Switch Bipolar Forceps _(CD957)
Predicate device K130669

Compared Items	Proposed Device (K210315) Single Use Hand Switch Monopolar Forceps with Smoke Evacuation	Predicate Device (K130669) Olsen Medical Bipolar and Monopolar Forceps	Result	Comments on difference/ equivalent evidence
Classification Name	Electrosurgical, Cutting and Coagulation Accessories	Electrosurgical, Cutting and Coagulation Accessories	Equivalent	
Regulation	878.4400	878.4400	Equivalent	
Common Name	Single Use Hand Switch Bipolar Forceps	Single Use Bipolar and Monopolar Forceps Multiple-Use Bipolar and	Equivalent	

		Monopolar Forceps		
Product Code	GEI	GEI	Equivalent	
Intended use	The device is intended to be used as active electrosurgical devices where bipolar electrosurgical coagulation is desired during surgery and are intended to grasp, manipulate coagulate selected soft tissue.	The OLSEN Medical Electrosurgical Monopolar and Bipolar Forceps are intended to be used as active electrosurgical devices where monopolar or bipolar electrosurgical cutting and coagulation is desired during surgery and are intended to grasp, manipulate cut or coagulate selected soft tissue.	Equivalent	Evidence: IFU
Prescription or OTC	Prescription Use	Prescription Use	Equivalent	
Indication for use	The device delivers electrosurgical current to target tissue for coagulation in electrosurgical procedure.	OLSENMedical® Electrosurgical Monopolar and Bipolar Forceps have been designed as active electrosurgical instruments to grasp, manipulate, cut or coagulate selected soft tissue. These stainless steel forceps are connected through a suitable active electrosurgical cable (bipolar or monopolar) to the specified output terminal of an electrosurgical generator.	Equivalent	Evidence: IFU

Sterility	ETO	Irradiation	Equivalent	ETO sterilization validation have done for this device. Evidence: EO validation report number R-EO2011
Usage	Single Use	Disposable and reusable	Equivalent	Evidence: IFU
Tip Material	Stainless Steel	Stainless Steel	Equivalent	Evidence: Material Technical Data Sheet
Size (distal tips)	0.1-1.2mm	0.5-1.5mm	Not Equivalent	Tip Size doesn't increase any risk for the product. Evidence: 955MVPE1N-2111122R.
Packaging	Tyvek Pouch	Tyvek Pouch	Equivalent	Evidence: IFU
Electrical Safety Testing	IEC 60601-2-2	IEC 60601-2-2	Equivalent	Evidence: DSS_GZES200802563702-IEC 60601-2-2
Energy delivery	Monopolar electrosurgical Forceps which delivers electrosurgical current to target tissue.	Monopolar or bipolar electrosurgical Forceps which delivers electrosurgical current to target tissue.	Equivalent	Evidence: test report number 954MVPE2N-2012196R
Rated Accessory Voltage	2.0kVp	The bipolar forceps are intended for use with a maximum voltage of 500 volts while the monopolar forceps have a maximum voltage of 2000 volts.	Equivalent	Evidence: Accelerated aging test report
Biocompatibility	Non irritant, non sensitive to skin, non toxic to cells	Non irritant, non sensitive to skin, non toxic to cells	Equivalent	Evidence: Biocompatibility test report
Shelf life	3 years	3 years	Equivalent	Evidence: Labeling
Target population	All patients, no specific restriction	All patients, no specific restriction	Equivalent	Evidence: IFU
Where used	Hospitals	Hospitals	Equivalent	Evidence: IFU

We conclude that proposal devices are substantial equivalence to predicate devices.

9. Performance Testing Data

Validation and Verification testing was performed on device sterility in accordance with

ISO11135:2014/AMD 1:2018 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices .

Performance Testing included comparative device use on porcine tissue: kidney, liver and muscle for both Cut mode and Coagulation mode in accordance with the Premarket Notification (510(k) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff, Document issued on August 15, 2016.

10. Safety and Biocompatibility testing data

Electrical Safety complies with

IEC 60601-1:2005+AMD1:2012
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014
Medical electrical equipment - Part 1 -2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-2-2:2017
Medical electrical equipment - Part 2- 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

The proposed devices are an external device that contacts tissue/bone/dentin for limited contact duration (less than 24 hours). No biologically significant effect was observed in tests conducted in accordance with following ISO 10993 standards for Cytotoxicity, Sensitization, Intracutaneous reactivity, Material-mediated pyrogenicity and Acutesystemic toxicity.

ISO 10993-5:2009
Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010
Biological evaluation of medical devices — Part 10: Tests for skin sensitization

ISO 10993-11:2017
Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

11. Conclusion

The proposed Modern Medical Monopolar and Bipolar Forceps is similar in design as its predicates. The Modern Medical Forceps are sterilized using equivalent material and processes as its predicates. The subject devices also have same intended use and performance characteristics as their predicates. No new technological characteristics were introduced and as such, the proposed forceps do not raise new types of safety and effectiveness issues as compared to the predicates.