April 18, 2023

Deltronix Equipamentos Ltda
% Mr. Bruno Milhoci
Regulatory Affairs Specialist
Passarini Regulatory Affairs
PR Serviços Regulatórios Administrativos Ltda
Rua Alice Aem Saadi, 855/ 2404
Ribeirao Pret, SP 14096-570
Brazil

Re: K223784
Trade/Device Name: Precision TC2, Precision TC3, Precision TC4, SEG 100, SEG 150, SEG 200
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 16, 2023
Received: March 23, 2023

Dear Mr. Milhoci:

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: 2023.04.18 11:55:59 -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
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)*
K223784

Device Name
Precision TC2, Precision TC3, Precision TC4, SEG 100, SEG 150, SEG200

Indications for Use *(Describe)*
The Deltronix Precision and SEG are a high frequency electrosurgical generators intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.

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

ADMINISTRATIVE INFORMATION

Sponsor/Manufacturer Name	Deltronix
Contact Person and Preparer	Bruno Milhoci. Regulatory Affairs Specialist Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda E-Mail: bruno@rapassarini.com.br Telephone +55 (16) 3421 8488
Date Prepared	DEC -16 2022

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Precision TC2, Precision TC3, Precision TC4, SEG 100, SEG 150, SEG200
Common Name	Electrosurgical Generator
Regulation Number	21 CFR 878.4400
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class	Class II
Product Code	GEI

IDENTIFICATION PREDICATE DEVICE

Trade/ Proprietary Name	VALLEYLAB FORCE FX
Common Name	Electrosurgical Generator
Regulation Number	21 CFR 878.4400
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class	Class II
Product Code	GEI
510(k) Number	K944692

IDENTIFICATION OF REFERENCE DEVICE PREDICATE

Trade/ Proprietary Name	Valleylab FX8
Common Name	Electrosurgical Generator
Regulation Number	21 CFR 878.4400
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class	Class II
Product Code	GEI
510(k) Number	K172757

INDICATIONS FOR USE

The Deltronix Precision and SEG are a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.

SUBJECT DEVICE DESCRIPTION

The electrosurgical generators of Precision and SEG lines are intended to cut and electrosurgical coagulation of living human tissues. This objective is achieved through the power supply at high frequency. The electrosurgical generator of the Precision line may coagulate by using both monopolar technique and bipolar technique.

Electrosurgical generators of the Precision and SEG lines and accessories should be used only by qualified and trained medical professionals in the use of electrosurgical equipment and surgical technique to be held.

TECHNOLOGICAL CHARACTERISTICS

The subject device and the predicate devices have the same intended use and technological characteristics.

Differences in the design features between the subject devices and the primary predicate devices K944602, and the reference predicate device K172757 are addressed by comparison to the reference devices as listed in the table below:

Table 5.1: Substantial Equivalence comparison

Description	Deltronix Precision TC4	Deltronix Precision TC3	Deltronix Precision TC2	Deltronix SEG100	Deltronix SEG150	Deltronix SEG200	Valleylab FX / K944602	Valleylab FX8 / K172757
Indications for Use	The Deltronix Precision and SEG are a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.	The Deltronix Precision and SEG are a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.	The Deltronix Precision and SEG are a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.	The Deltronix Precision and SEG are a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.	The Deltronix Precision and SEG are a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.	The Deltronix Precision and SEG are a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.	The Valleylab Force FX-C Electrosurgical Generator is an isolated output electrosurgical generator that provides power for cutting, desiccating, and fulgurating tissue during bipolar and monopolar surgery.	The Valleylab FX8 FX Series Energy Platform is a high-frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.
Prescription or OTC	Prescription only	Prescription only	Prescription only	Prescription only	Prescription only	Prescription only	Prescription only	Prescription only
ESU								
Major Functions	Bipolar Monopolar Impedance monitor Continuity monitor	Bipolar Monopolar Impedance monitor Continuity monitor	Bipolar Monopolar Impedance monitor Continuity monitor	Bipolar Monopolar Impedance monitor Continuity monitor	Bipolar Monopolar Impedance monitor Continuity monitor	Bipolar Monopolar Impedance monitor Continuity monitor	Bipolar Monopolar Impedance monitor Continuity monitor	Bipolar Monopolar Impedance monitor Continuity monitor
Performance								
Output frequency	Bipolar precise 400KHz Bipolar standard 400KHz Bipolar Macro 400KHz Monopolar Cut Pure Hi 400KHz Monopolar Cut Pure Low 400KHz Monopolar Blend1 400KHz Monopolar Blend2 400KHz	Bipolar precise 400KHz Bipolar standard 400KHz Bipolar Macro 400KHz Monopolar Cut Pure Hi 400KHz Monopolar Cut Pure Low 400KHz Monopolar Blend1 400KHz Monopolar Blend2 400KHz	Bipolar precise 400KHz Bipolar standard 400KHz Bipolar Macro 400KHz Monopolar Cut Pure Hi 400KHz Monopolar Cut Pure Low 400KHz Monopolar Blend1 400KHz Monopolar Blend2 400KHz	Bipolar precise 400KHz Bipolar standard 400KHz Bipolar Macro 400KHz Monopolar Cut Pure Hi 400KHz Monopolar Cut Pure Low 400KHz Monopolar Blend1 400KHz Monopolar Blend2 400KHz	Bipolar precise 400KHz Bipolar standard 400KHz Bipolar Macro 400KHz Monopolar Cut Pure Hi 400KHz Monopolar Cut Pure Low 400KHz Monopolar Blend1 400KHz Monopolar Blend2 400KHz	Bipolar precise 400KHz Bipolar standard 400KHz Bipolar Macro 400KHz Monopolar Cut Pure Hi 400KHz Monopolar Cut Pure Low 400KHz Monopolar Blend1 400KHz Monopolar Blend2 400KHz	Bipolar precise 470KHz Bipolar Standard 470KHz Bipolar Macro 470KHz Monopolar Cut Low 390KHz Monopolar Cut Pure 390KHz Monopolar Cut Blend 390KHz Monopolar Coag Disiccate 390KHz	Bipolar precise 470KHz Bipolar Standard 470KHz Bipolar Macro 470KHz Monopolar Cut Low 390KHz Monopolar Cut Pure 390KHz Monopolar Cut Blend 390KHz Monopolar Coag Disiccate 390KHz

	Monopolar Blend3 400KHz Monopolar Coag Disiccate 400KHz Monopolar Coag Spray 400KHz Monopolar Coag Fulgurate 400KHz	Monopolar Blend3 400KHz Monopolar Coag Disiccate 400KHz Monopolar Coag Spray 400KHz Monopolar Coag Fulgurate 400KHz	Monopolar Blend3 400KHz Monopolar Coag Disiccate 400KHz Monopolar Coag Spray 400KHz Monopolar Coag Fulgurate 400KHz	Monopolar Blend3 400KHz Monopolar Coag Disiccate 400KHz Monopolar Coag Spray 400KHz Monopolar Coag Fulgurate 400KHz	Monopolar Blend3 400KHz Monopolar Coag Disiccate 400KHz Monopolar Coag Spray 400KHz Monopolar Coag Fulgurate 400KHz	Monopolar Blend3 400KHz Monopolar Coag Disiccate 400KHz Monopolar Coag Spray 400KHz Monopolar Coag Fulgurate 400KHz	Monopolar Coag Fulgurate 390KHz Monopolar Coag LCF Fulgurate 240KHz Monopolar Coag Spray 390KHz	Monopolar Coag Fulgurate 390KHz Monopolar Coag LCF Fulgurate 240KHz Monopolar Coag Spray 390KHz
Waveform	Sinusoidal	Sinusoidal	Sinusoidal	Sinusoidal	Sinusoidal	Sinusoidal	Sinusoidal	Sinusoidal
Channels	2	2	2	1	1	1	2	2
Power output	400W	300W	200W	100W	150W	200W	300W	300W
Voltage output	4185 Volts	4185 Volts	4185 Volts	4185 Volts	4185 Volts	4185 Volts	4853 Volts	4853 Volts
Crest Factor	1.7 to 8.2	1.7 to 8.2	1.7 to 8.2	1.7 to 8.2	1.7 to 8.2	1.7 to 8.2	1.4 to 7.7	1.4 to 7.7
Input power (VA)	1253 VA Max	1253 VA Max	1253 VA Max	1253 VA Max	1253 VA Max	1253 VA Max	924 VA Max	924 VA Max

The subject device Deltronix Precision and SEG are substantially equivalent to the primary predicate device K944602, and reference device K172757, in designs functionalities. The reference device is K172757.

CONCLUSION

The documentation submitted in this premarket notification demonstrates that the subject devices have comparable features and performance and, therefore, are substantially equivalent to the identified predicate devices.