November 10, 2021

Intelis Instruments Ltd.
% Amit Goren
Regulatory Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
18 Hata'as Str., Suite 21
Kfar Saba, 4442518
Israel

Re: K212107
Trade/Device Name: Reverso
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 10, 2021
Received: October 13, 2021

Dear Amit Goren:

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,

for 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)*

K212107

Device Name
Reverso

Indications for Use *(Describe)*

The Reverso is a non-invasive device intended for use in dermatological procedures requiring ablation and resurfacing of the skin.

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

REVERSO DEVICE

510(k) Number K212107

Applicant Name:

Company Name: Intelis Instruments Ltd.
Address: HaOman 12
Hadera, 3850172
Israel
Tel: +972-528701672
E-mail: amit@asteinrac.com

Contact Person:

Official Correspondent: Amit Goren
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 18 Hata'as Str.
Kfar Saba 4442518
Israel
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: November 10, 2021

Trade Name: Reverso

Classification Name: CFR Classification section 878.4400;

(Product code GEI)

Classification: Class II Medical Device

Predicate Device:

The Reverso device is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
Venus Concept USA Inc.	Venus Viva MD	K201164

Device Description:

The Reverso device is a tabletop computerized system comprised a console (main unit) and Applicator with detachable single-use tips. The system delivers RF energy in a fractional manner to the skin of a treatment area for ablation and resurfacing of the skin. The Reverso device provides individual adjustments of energy settings, tip pattern, pulse profile to achieve appropriate efficiency and safety for each eligible patient.

The device console includes a power supply unit, controller card and LCD screen with touch panel.

The Reverso device Applicator is designed for use in dermatological procedures requiring ablation and resurfacing of the skin. The applicator is hand- held and ergonomically designed for the treatment requiring ablation and resurfacing of the skin. The applicator is connected to the system via a cable. When not in use, the applicator can be placed within the applicator holder positioned on the system console.

The Reverso Applicator is compatible with two types of fractional RF tip heads; 80 pin tip head and 160 pin tip head.

Following are the Reverso device specifications:

RF Max Output Power:	10 Watt
RF Output Frequency:	640[KHz]
Dimension:	31.8cm W x 31.5cm D x 31.5cm H [12.4" W x 12.3" D x 12.3" H]
Weight:	6 Kg (13.2 lbs.)
Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC

Intended Use/Indication for Use:

The Reverso device is a non-invasive device intended for use in dermatologic procedures requiring ablation and resurfacing of the skin.

Performance Standards:

The Reverso device has been tested and complies with the following voluntary recognized standards:

- ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2 Edition 4.0 2014-02 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 Edition 6.0 2017-03 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.

- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Non-Clinical (Bench) Performance Data:

Performance bench tests were conducted to evaluate and compare the Reverso device RF performance specifications to the specific design requirements and to the RF performance specifications of the predicate device. The results of the bench test demonstrate that the Reverso device complies with the design requirements comprise similar RF output specifications as the predicate devices and therefore, is substantially equivalent to the predicate devices.

The safety and effectiveness of the Reverso device were further evaluated in an ex-vivo tissue testing for dermatological procedures requiring skin ablation and skin resurfacing. The study was conducted on human abdomen tissues following an abdominoplasty surgery and included a single treatment utilizing the Reverso device in its final, finished version. The predicate device; the Venus Viva MD device (Subject of K201164) was used for comparison utilized in

similar operation condition on similar ex-vivo tissues. Untreated tissue was used as a control. Treatment was followed by biopsy sampling of slices trimmed along the pin's penetration path and collection immediately stained by H&E staining to visualize the tissue ablation and coagulation patterns. The *ex-vivo* study results demonstrated that the Reverso device is safe for use and effective in achieving the specified indications of dermatological skin ablation and skin resurfacing. Furthermore, the histology results of the subject device tissue samples were compared with the histology results of the predicate device tissue samples. The comparison demonstrated an equivalency in ablation and coagulation characteristics.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The Reverso device is substantially equivalent to the Venus Viva MD Device (manufactured by Venus Concept USA Inc. and the subject of K201164). The subject device and predicate device share the same underlying technology of fractional RF, same RF output specifications and same operational principals.
A comparison table is provided below comparing the intended use and basic technological characteristics of the Reverso device to the intended use and basic technological characteristics of the predicate device.

Technological Characteristic	**Reverso Device Intelis Instruments Ltd. (Subject Device)**	**Venus Viva MD™ Venus Concept USA Inc. K201164 (Predicate Device)**
Product Code, Class	GEI Class II	GEI Class II
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Indications for Use	The Reverso is a non-invasive device intended for use in dermatological procedures requiring ablation and resurfacing of the skin.	The Venus Viva MD is a non-invasive device intended to be used by aesthetic- related physicians or dermatologists . When used with the Viva MD applicator, the Venus Viva MD Device is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.
Anatomical Sites	Body parts requiring treatment as specified in the indication for use	idem
Target Population	Adults requiring treatment as specified in the indication for use	idem
Environment Used	Hospital or Clinic setting	idem
Energy Used / Delivered	RF energy	idem
Design:	Fractional RF: Use of RF energy delivered through a matrix of multiple pin electrodes allocated on the applicator tip	idem
- Mechanism of Action	Treatment is based on fractional sub- necrotic heating of papillary and reticular dermis triggering slow collagen remodeling.	idem
- Components	Tabletop Console including : • Display panel • Main CPU • Power supply Reverso applicator. The applicator comprises the applicator handle, trigger, RF generator and	Tabletop Console including: • Display panel • Main CPU • Power supply • RF Generator Two optional applicators: • Viva MD applicator. The applicator comprises the applicator handle, trigger, RF generator and

Technological Characteristic	**Reverso Device Intelis Instruments Ltd. (Subject Device)**	**Venus Viva MD™ Venus Concept USA Inc. K201164 (Predicate Device)**
	detachable electrode tip (160 pin or 80 pin).	detachable electrode tip (160 pin or 80 pin). • Diamondpolar Applicator **(irrelevant for this 510(K) substantial equivalent discussion)**
RF Performance specifications	RF Frequency: 0.46 MHz • Energy per pin: 62 mJ/pin (160 pin tip) 124 mJ/pin (80 pin tip)	idem
- System Dimensions	31.8cm W x 31.5cm D x 31.5cm H [12.4" W x 12.3" D x 12.3" H]	38cm W x 40cm D x 40cm H [14.8" W x 15.6" D x 15.6" H]
- Weight Platform weight Applicator weight	6 Kg (13.2 lbs.) Applicator – 0.3 Kg (0.66 lbs.)	8 Kg (17.6 lbs.) Applicator – N/A
Cable Dimensions:	170 cm	idem
Materials	Applicator Handle: PC Makrolon 2458 Tip outer body: PC Makrolon 2458 RF pin electrodes: Stainless steel 302.	idem
Standards Met	AAMI/ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-2-2 IEC 60601-1-6	idem
Biocompatibility	All materials are biocompatible	idem
Compatibility with Environment and Other Devices	Reverso is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem
Sterility	Provided non-sterile. The detachable, single use tip head is to be sterilized by the user close to treatment onset, using autoclaving sterilization technique.	idem
Electrical Safety	Power Requirements: 100-240 VAC 50-60 Hz	idem

Technological Characteristic	**Reverso Device Intelis Instruments Ltd. (Subject Device)**	**Venus Viva MD™ Venus Concept USA Inc. K201164 (Predicate Device)**
	The Reverso is compliant with the IEC 60601-1 standard.	
Mechanical Safety	The Reverso is compliant with the IEC 60601-1 standard.	idem
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	The Reverso is compliant with the IEC 60601-1 standard.	idem
Radiation Safety	The Reverso is compliant with the IEC 60601-1-2 (EMC Safety) standard.	Idem

The indications for use and technological characteristics of the Reverso device are substantially equivalent to the indications for use and technological characteristics of the predicate, the Venus Viva MD device (and the subject of K201164).

The design of and the components in the Reverso device, including the console (with the power supply unit, controller and display user interface) and the applicator (with cable, connector to console, handle and tip head) are identical to the design and components found in the predicate device, with similar to identical dimensions and weight.

The RF performance specifications (RF frequency, RF energy per pin, RF energy level) of the Reverso device were shown to be identical to those of the predicate device as demonstrated in the bench performance testing. Furthermore, the Reverso device and the predicate device demonstrated similar thermal effect over ex-vivo human tissues following a single treatment performed under similar RF performance specifications and similar operation conditions.

All of the identified device related hazards are of low risk and are mostly related with transient symptoms of erythema and edema which are resolved 24-72 hours post treatment.

Therefore, it can be deduced that the Reverso device is as safe and effective as the predicate device, and that no new safety or effectiveness issues are raised in regard to the subject device functionality.

The safety features and compliance with safety standards in the subject device are similar to the safety features and compliance with safety standards found in the predicate device.

Patient contact materials are the same between the subject device and its predicate device. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns.

Furthermore, the Reverso device underwent performance testing, including software validation testing (provided in Section 16), Electrical and Mechanical Safety testing according to IEC 60601-1, Electromagnetic Compatibility testing according to IEC 60601-1-2 and Usability according to IEC 60601-1-6 (provided in Section 17), bench and *ex-vivo* testing to evaluate and compare the RF performance specifications and the thermal effect of the device on target tissues to that of the predicate device (provided in Section 18). These performance tests demonstrated that the minor differences in the device design and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the Reverso device is substantially equivalent to the predicate device, the Venus Viva MD, FDA cleared under 510(k) K201164, and therefore, may be legally marketed in the USA.