January 22, 2025

Indiba S.A.U
% Amit Goren
Head of Regulatory Affairs
A.Stein Regulatory Affairs Consulting Company Ltd.
18 Hata'as St.
Kfar Saba, 4442518
Israel

Re: K243139
Trade/Device Name: Reverso Pro System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 16, 2024
Received: December 16, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2025.01.22 08:52:50 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K243139

Device Name
Reverso Pro System

Indications for Use *(Describe)*
The Reverso Pro System is a non-invasive device intended to be used by aesthetic-related physicians or dermatologists.

- The Reverso Pro System utilizing the Reverso Applicator is a non-invasive device intended for use in dermatological procedures requiring ablation and resurfacing of the skin.
- The Reverso Pro System utilizing the Quadro RF Applicator is indicated to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The massage device is intended to provide a temporary reduction in the appearance of cellulite.

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.

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510(K) SUMMARY

REVERSO PRO SYSTEM

510(k) Number K243139

Applicant Name:

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Date Prepared: January 22, 2025

Trade Name: Reverso Pro System

Classification Name: CFR Classification section 878.4400;

(Product codes GEI, PBX)

Classification: Class II Medical Device

Predicate Devices:

The Reverso Pro system is substantially equivalent to the following predicate devices;

Manufacturer	Device	510(k) No.
Intelis Instruments Ltd.	Reverso Device	K212107
Venus Concept USA Inc.	Venus Viva MD	K201164
InMode MD Ltd.	InMode PLUS System	K172302

Reverso Pro System 510(k) file
510(k) Summary

Device Description:

The Reverso Pro System, positioned on a rolling cart, is a computerized system comprised of a console (main unit) and two Applicators: The Reverso Applicator with detachable single-use tips and the Quadro RF Applicator. The system using the Reverso Applicator delivers RF energy in a fractional manner to the skin of a treatment area for ablation and resurfacing of the skin, or using the Quadro RF Applicator in a continuous wave manner to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The Reverso Pro System provides individual adjustments of energy settings and treatment time, and, in the Reverso mode, it also enables the adjustment of tip pattern and pulse profile, to achieve appropriate efficiency and safety for each eligible patient.

The system console includes a power supply unit, controller card and LCD screen with touch panel. The Reverso Pro System Applicators are designed for use in dermatological procedures, they are hand-held and ergonomically designed for the treatment requirements. The applicators are connected to the system via a separate cable, each. When not in use, the applicators can be placed within the applicator holder, where the Reverso Applicator is positioned on the system console and the Quadro RF Applicator is positioned on the rolling cart. The Reverso Applicator is compatible with five types of fractional RF tip heads: 44, 80, 88, 160 pin tip head and 176 pin tip head.

The Quadro RF Applicator is emitting continues RF energy through a set of two pairs of stainless steel, RF electrodes. The applicator is hand-held and ergonomically designed to induce heat of the skin and beneath tissues for topical heating sensation.

Following are the Reverso Pro System specifications:

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
RF Max Output Power:	10 Watt - Fractional Reverso 50 Watt - Quadro RF
RF Output Frequency:	640 KHz Fractional Reverso, 1 MHz Quadro RF

Intended Use/Indication for Use:

The Reverso Pro System is a non-invasive device intended to be used by aesthetic-related physicians or dermatologists.

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

- The Reverso Pro System utilizing the Quadro RF Applicator is indicated to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The massage device is intended to provide a temporary reduction in the appearance of cellulite.

Performance Standards:

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

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version 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 Pro System 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 comprises similar RF output specifications as the predicate device and therefore, is substantially equivalent to the predicate devices.

The safety and effectiveness of the Reverso Pro System with the Quadro RF Applicator were further evaluated in a skin temperature test. The device was applied on 3 human volunteers, utilizing low and high RF power settings and skin temperatures were measured throughout the treatment time. The study results demonstrated that the Reverso Pro System with the Quadro RF Applicator is capable of maintaining a skin surface temperature of 40°-45°C for the entire treatment time.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The Reverso Pro System is substantially equivalent to the primary device, Reverso device (manufactured by Intelis Instruments Ltd., and the subject of K212107) when it is equipped with the microneedling heads. The Venus Viva MD Device (manufactured by Venus Concept USA Inc. and the subject of K201164) serves as the secondary predicate for the Quadro RF applicator, and

the InMode PLUS System (manufactured by InMode MD Ltd. and the subject of K172302) serves as a third predicate to justify the Quadro RF topical heating indication. The subject device and predicate devices share the same underlying technology of fractional and CW RF, same RF output specifications and same operational principles.

A comparison table is provided below comparing the intended use and basic technological characteristics of the Reverso Pro System to the intended use and basic technological characteristics of the predicate devices.

Technological Characteristic	Reverso Pro system Indiba S.A.U. K234139 (Subject Device)	Reverso Device Intelis Instruments Ltd. K212107 (Primary Predicate Device)	Venus Viva MD™ Venus Concept USA Inc. K201164 (Secondary Predicate Device)	InMode PLUS System InMode MD Ltd. K172302 (Third Predicate Device)
Product Code, Class	GEI, PBX Class II	GEI Class II	GEI Class II	PBX, ISA Class II
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400, 890.5660
Indications for Use	The Reverso Pro System is a non-invasive device intended to be used by aesthetic related physicians or dermatologists . The Reverso Pro System, when used with the Reverso applicator, is indicated for use in dermatologic procedures, requiring ablation and resurfacing of the skin. The Reverso Pro System utilizing the Quadro RF Applicator is indicated to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The massage device is intended to provide a temporary reduction in the appearance of cellulite.	The Reverso device 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 . The Venus Viva MD device when used with the Diamondpolar applicator, is intended for use in dermatological and surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin type I-IV. 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.	The InMode PLUS System with the PLUS/PLUS90/PLUS-PLUS Hand pieces is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation
Anatomical Sites	Body parts requiring treatment as specified in the indication for use	idem	idem	idem

Technological Characteristic	**Reverso Pro system Indiba S.A.U. K234139 (Subject Device)**	**Reverso Device Intelis Instruments Ltd. K212107 (Primary Predicate Device)**	**Venus Viva MD™ Venus Concept USA Inc. K201164 (Secondary Predicate Device)**	**InMode PLUS System InMode MD Ltd. K172302 (Third Predicate Device)**
Target Population	Adults requiring treatment as specified in the indication for use	idem	idem	idem
Environment Used	Hospital or Clinic setting	idem	idem	idem
Energy Used / Delivered	Fractional RF energy Bi-polar RF energy	Fractional RF energy	Fractional RF energy Bi-polar RF energy	Bi-polar RF energy
Design:	The Reverso Pro System comprises a console, screen, connectors, designated cart and two treatment applicators: Reverso Fractional RF: Use of RF energy delivered through a matrix of multiple pin electrodes allocated on the applicator tip. Quadro Bi-polar RF: Use of two sets of Bi-polar RF electrodes for the delivery of RF energy for local dermal heating.	The Reverso device comprises a console, screen, connectors, and the Reverso Fractional RF applicator. Reverso Fractional RF: Use of RF energy delivered through a matrix of multiple pin electrodes allocated on the applicator tip.	The Venus Viva MD device comprises a console, screen, connectors and two treatment applicators: Viva MD Fractional RF: Use of RF energy delivered through a matrix of multiple pin electrodes allocated on the applicator tip. Dimondpolar Bi-polar RF: Use of two sets of Bi-polar RF electrodes for the delivery of RF energy for local dermal heating.	The InMode PLUS System comprises a console, screen, connectors and three treatment applicators: • InMode PLUS hand piece • InMode PLUS90 hand piece • InMode PLUS-PLUS hand piece

Technological Characteristic	**Reverso Pro system Indiba S.A.U. K234139 (Subject Device)**	**Reverso Device Intelis Instruments Ltd. K212107 (Primary Predicate Device)**	**Venus Viva MD™ Venus Concept USA Inc. K201164 (Secondary Predicate Device)**	**InMode PLUS System InMode MD Ltd. K172302 (Third Predicate Device)**
- Mechanism of Action	Fractional RF treatments: Treatment is based on fractional sub- necrotic heating of papillary and reticular dermis triggering slow collagen remodeling. Bi-polar RF energy is being emitted to the skin by two sets of RF electrodes, generating local tissue heating for collagen remodeling and tissue regeneration.	Fractional RF treatments: Treatment is based on fractional sub- necrotic heating of papillary and reticular dermis triggering slow collagen remodeling.	Fractional RF treatments: Treatment is based on fractional sub- necrotic heating of papillary and reticular dermis triggering slow collagen remodeling. Bi-polar RF energy is being emitted to the skin by two sets of RF electrodes, generating local tissue heating for collagen remodeling and tissue regeneration.	Bi-polar RF energy is being emitted to the skin by two RF electrodes, generating local tissue heating for topical heating.
- Components	Tabletop/Cart positioned Console including : • Display panel • Main CPU • Power supply • Applicator cradle • RF generator Two optional applicators: The Reverso Applicator. The applicator comprises the applicator handle, trigger, RF generator, indication LEDs and detachable electrode tip heads (44, 80, 88, 160 or 176 pins). The Quadro RF Applicator. The applicator comprises the	Tabletop Console including : • Display panel • Main CPU • Power supply • Applicator cradle The Reverso applicator. The applicator comprises the applicator handle, trigger, RF generator and detachable electrode tip heads (160 pin or 80 pin).	Tabletop Console including: • Display panel • Main CPU • Power supply • RF Generator • Applicator cradle Two optional applicators: Viva MD applicator. The applicator comprises the applicator handle, trigger, RF generator and detachable electrode tip (80 pin or 160 pin).	Tabletop Console including: • Display panel • Main CPU • Power supply • RF Generator • Applicator cradle Three optional applicators: • InMode PLUS hand piece • InMode PLUS90 hand piece • InMode PLUS-PLUS hand piece

Technological Characteristic	**Reverso Pro system Indiba S.A.U. K234139 (Subject Device)**	**Reverso Device Intelis Instruments Ltd. K212107 (Primary Predicate Device)**	**Venus Viva MD™ Venus Concept USA Inc. K201164 (Secondary Predicate Device)**	**InMode PLUS System InMode MD Ltd. K172302 (Third Predicate Device)**
	applicator handle, trigger, indication LEDs and 2 sets of RF electrodes.		Diamondpolar Applicator. The applicator comprises the applicator handle, trigger, and 2 sets of RF electrodes.	
RF Performance specifications	Reverso Applicator: 0.46 MHz Quadro RF Applicator: 1.0 MHz	Reverso applicator: 0.46 MHz	Viva MD Applicator: 0.46 MHz Dimondpolar applicator: 1.0MHz	All PLUS Applicators: 1.0MHz
- System Dimensions	31.8cm W x 31.5cm D x 31.5cm H [12.4" W x 12.3" D x 12.3" H]	idem	38cm W x 40cm D x 40cm H [14.8" W x 15.6" D x 15.6" H]	Not Applicable
Cable Dimensions:	170 cm	idem	idem	Not Applicable
Materials	Applicator Handle: PC Makrolon 2458 Tip outer body: PC Makrolon 2458 RF pin electrodes: Stainless steel 302.	idem	idem	Not Applicable
Standards Met	AAMI/ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-2-2 IEC 60601-1-6	idem	idem	idem
Biocompatibility	All materials are biocompatible	idem	idem	idem
Compatibility with Environment and Other Devices	Reverso Pro is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem	idem	idem

Technological Characteristic	**Reverso Pro system Indiba S.A.U. K234139 (Subject Device)**	**Reverso Device Intelis Instruments Ltd. K212107 (Primary Predicate Device)**	**Venus Viva MD™ Venus Concept USA Inc. K201164 (Secondary Predicate Device)**	**InMode PLUS System InMode MD Ltd. K172302 (Third Predicate Device)**
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	idem	idem
Electrical Safety	Power Requirements: 100-240 VAC 50-60 Hz The Reverso Pro is compliant with the IEC 60601-1 standard.	idem	idem	idem
Mechanical Safety	The Reverso Pro is compliant with the IEC 60601-1 standard.	idem	idem	idem
Chemical Safety	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Thermal Safety	The Reverso Pro is compliant with the IEC 60601-1 standard.	idem	idem	idem
Radiation Safety	The Reverso Pro is compliant with the IEC 60601-1-2 (EMC Safety) standard.	Idem	Idem	

The indications for use and technological characteristics of the Reverso Pro System are substantially equivalent to the indications for use and technological characteristics of the predicate devices.

The design of and the components in the Reverso Pro System, including the console (with the power supply unit, controller and display user interface), screen, applicator cradles, applicator connectors and the applicator handle - The Reverso fractional RF applicator with detachable tip heads, is close to identical to the design of the Reverso device (FDA cleared Device, K212107) and the design of Quadro RF Applicator is similar to the design of the Dimondpolar applicator as in the secondary predicate device, the Venus Viva MD device, FDA cleared Device (510(k) document No. K201164).

The RF performance specifications (RF frequency, RF energy level) of the Reverso Pro System were shown to be identical to those of the predicate device as demonstrated in the bench performance testing. Furthermore, the Reverso Pro System with the Quadro RF Applicator demonstrated the ability to maintain therapeutic temperatures of the skin for topical heating purposes.

Therefore, it can be deduced that the Reverso Pro System is as safe and effective as the predicate devices, 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 devices.

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

Furthermore, the Reverso Pro System underwent performance testing, including software validation testing, 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, bench and human skin 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. These performance tests demonstrated that the minor differences in the system design and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the Reverso Pro System is substantially equivalent to the predicate devices and therefore, may be legally marketed in the USA.