January 24, 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: K241107
Trade/Device Name: Indiba Diathermia Radiofrequency Deep Care Device (Deep care IDC0409/EVONY); Indiba Diathermia Radiofrequency Activ Device (Activ ACT0309/CT9)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: October 28, 2024
Received: October 29, 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: 2025.01.24 15:20:56 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241107

Device Name

Indiba Diathermia Radiofrequency Deep Care Device
(IDC0409/EVONY);
Indiba Diathermia Radiofrequency Activ Device (ACT0309/Activ CT9)

Indications for Use *(Describe)*

The Indiba Diathermia Radiofrequency Deep Care/Activ devices are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation.
The massage device provided 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.

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INDIBA DIATHERMIA RADIOFREQUENCY ACTIV DEVICE, INDIBA DIATHERMIA RADIOFREQUENCY DEEP CARE DEVICE

510(K) SUMMARY

510(k) Number K241107

Applicant Name:

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Date Prepared: October 28, 2024

Trade Name: Activ CT9 device, EVONY device

Classification Name: CFR Classification section 878.4400;

(Product code PBX)

Classification: Class II Medical Device

Predicate Devices: The INDIBA Diathermia Radiofrequency Activ Device model (Activ CT9 device) and The INDIBA Diathermia Radiofrequency Deep Care device model (EVONY device) are substantially equivalent to the following predicate devices;

Manufacturer	Device	510(k) No.
Indiba S.A.U.	Activ 902	K161458
Indiba S.A.U.	ELITE	K161458

Device Description:

The INDIBA Diathermia Radiofrequency Activ device model (Activ CT9 device) and the INDIBA Diathermia Radiofrequency Deep Care device model (EVONY device), are non-invasive, diathermy, therapeutic devices, which employ RF current.

The device models consist of a console which generates a radiofrequency current which is delivered to the patient, in monopolar form, through two different types of electrodes, stainless steel conductive resistive electrodes (RES), and thin layer insulated capacitive electrodes (CAP). The electrodes are inserted into a handle, and the handle is connected to the console by a designated cable, the generated current flows through the patient and returns to the device through the neutral return electrode.

The Activ CT9 device model is equipped with additional massage applicators which provide mechanical massage for the temporary reduction in the appearance of cellulite.

The INDIBA Diathermia Radiofrequency Activ device model and the INDIBA Diathermia Radiofrequency Deep Care device model comprise a user interface (touchscreen) to facilitate the user device operation and to enable the user to predefine the device treatment settings.

The INDIBA Diathermia Radiofrequency Deep Care device model device incorporates smart handles and smart electrodes, which enables the device to automatically identify the connected applicators and enables their operation via the control options on the touchscreen.

The EVONY device provides a new temperature tracking tool enabling the user to track the patient skin temperature during the treatment time.

Improvements were performed in both device models in the console design and in the graphical user interface (GUI).

New applicators were introduced for the INDIBA Diathermia Radiofrequency Activ device model – the Fascia and Target electrodes and for the INDIBA Diathermia Radiofrequency Deep Care device model – the Sculpture electrodes. The new electrodes behave and operate in the same manner as the already FDA cleared RES and CAP electrodes.

All of the device improvements and modifications do not pose any new risks for the device safety and effectiveness.

The Activ CT9 and the EVONY device models, bearing the same technical specifications:

	Subject device models	
Feature	 Activ CT9	 EVONY
Weight	9.5 kg	50 kg (includes trolley)
Size	400 mm (width) 530 mm (depth) 150 mm (height, with display folded)	670 mm (width) 530 mm (depth) 1370 mm (height)
Input Mains Supply	(100 – 240) VAC 50/60 Hz	(100 – 240) VAC 50/60 Hz
Display	8" color TFT (800 x 480 pixels)	21.5" color TFT (1920 x 1080 pixels)
User input interface	Touchscreen	Touchscreen
Output frequency in RES mode	448 kHz	448 kHz
Output frequency range in CAP mode	448 kHz	448 kHz
Maximum output power in RES mode	200 W	200 W
Maximum output power in CAP mode	450 VA	450 VA
Temperature range for operation:	+10ºC to +40ºC	+10ºC to +40ºC
Temperature range for storage and transport:	-20ºC to +50ºC	-20ºC to +50ºC
Timer range:	0 – 99 minutes	0 – 99 minutes

Intended Use/Indication for Use:

The Indiba Diathermia Radiofrequency devices are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation.

The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.

Performance Standards:

The INDIBA Diathermia Radiofrequency Activ device model 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.

The INDIBA Diathermia Radiofrequency Deep Care device model 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

Non-Clinical (Bench) Performance Data:

The following validation activities were performed:

- Software Verification and Validation Testing
- Electrical safety and EMC testing
- Power control and RF accuracy testing
- Labeling Verification and Validation Testing

All of the validation activities were performed using the same testing techniques and principles as performed using the predicate device models. The results of the above listed validation activities conclude that the INDIBA Diathermia Radiofrequency Activ device model and the INDIBA Diathermia Radiofrequency Deep Care device model are safe and effective for their intended use and user population (both users and patients) and that the modified device models are substantially equivalent to their respective predicate devices.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Biocompatibility

All of the modified device models' materials which come in direct contact with the patient skin are biocompatible and identical to the materials used in the manufacturing of the predicate device models all manufactured by INDIBA S.A.U.

Substantial Equivalence:

The INDIBA Diathermia Radiofrequency Activ device model and the INDIBA Diathermia Radiofrequency Deep Care device model are substantially equivalent to the INDIBA Diathermia Radiofrequency Activ 902 device model and to the INDIBA Diathermia Radiofrequency ELITE device model respectively, all manufactured by INDIBA S.A.U., and the subject of K161458. The subject device models and predicate device models share the same underlying technology of mono-polar RF, the same RF output specifications and same operational principles.

A comparison table is provided below comparing the intended use and basic technological characteristics of the subject device models to the intended use and basic technological characteristics of the predicate device models.

	ELITE **Predicate Device;** **INDIBA S.A.U** **K161458**	**EVONY Device** **Subject device;** **INDIBA S.A.U**	**Activ 902** **Predicate Device;** **INDIBA S.A.U** **K161458**	**Activ CT9 Device** **Subject device;** **INDIBA S.A.U**
Device Technological Characteristics				
Device description / Design	The INDIBA Diathermia Radiofrequency Device is a therapeutic device for Deep, non-invasive diathermy, consists of a tabletop console which generates a radiofrequency current which is delivered to the patient. The device is line powered & software controlled. Mono-polar radiofrequency (RF) current is generated in the console and emitted to the patient's skin by two different RF electrode types: RES & CAP. The RF current returns to the console through a neutral return electrode. The device comprises additional massage pieces that can be used to massage the skin for cellulite treatment.	The INDIBA Diathermia Radiofrequency Device, is a therapeutic device for Deep, non-invasive diathermy, consists of a main body (console and a touchscreen), and a CPU unit that is also incorpor ated in the main unit. The device is line powered & software controlled. The touchscreen comprises user interface and enables the user to predefine the device treatment settings and facilitate the user device operation. Mono-polar radiofrequency (RF) current is generated in the console and emitted to the patient's skin by two different RF electrode types: RES & CAP installed on a smart handle.	The INDIBA Diathermia Radiofrequency Device is a therapeutic device for Activ, non-invasive diathermy, consists of a tabletop console which generates a radiofrequency current which is delivered to the patient. The device is line powered & software controlled. Mono-polar radiofrequency (RF) current is generated in the console and emitted to the patient's skin by two different RF electrode types: RES & CAP. The RF current returns to the console through a neutral return electrode. The device comprises additional massage pieces that can be used to massage	The INDIBA Diathermia Radiofrequency Device, is a therapeutic device for Activ, non-invasive diathermy, consists of a tabletop console (console and a touchscreen) which generates a radiofrequency current which is delivered to the patient. The device is line powered & software controlled. The touchscreen comprises user interface and enables the user to predefine the device treatment settings and facilitate the user device operation. Mono-polar radiofrequency (RF) current is generated in

	ELITE Predicate Device; INDIBA S.A.U K161458	**EVONY Device Subject device; INDIBA S.A.U**	**Activ 902 Predicate Device; INDIBA S.A.U K161458**	**Activ CT9 Device Subject device; INDIBA S.A.U**
		The device comprises the sculpture electrodes for additional treatment options. The RF current returns to the console through a neutral return electrode.	the skin for cellulite treatment.	the console and emitted to the patient's skin by two different RF electrode types: RES & CAP. The device comprises the fascia electrodes for additional treatment options. The RF current returns to the console through a neutral return electrode. The device comprises additional massage pieces that can be used to massage the skin for cellulite treatment.
Device components	The ELITE Device model consists of the following components: • Console, which contains the following components: ○ RF Generator ○ Control unit (CPU)	The IDC0409 Device model consists of the following components: • Console, which contains the following components: ○ RF Generator	The Activ 902 Device model consists of the following components: • Console, which contains the following components: ○ RF Generator ○ Control unit (CPU)	The Activ CT9 Device model consists of the following components: • Console, which contains the following components: ○ RF Generator

	ELITE **Predicate Device;** **INDIBA S.A.U** **K161458**	**EVONY Device** **Subject device;** **INDIBA S.A.U**	**Activ 902** **Predicate Device;** **INDIBA S.A.U** **K161458**	**Activ CT9 Device** **Subject device;** **INDIBA S.A.U**
	○ Device bottom panel ○ Incorporated display screen ○ Outlets connectors for treatment handles and return electrode The ELITE Device accessories: • Handles • Diathermia treatment electrodes: ○ Thin-layer insulated electrodes (called "Capacitive" or "CAP" electrodes by INDIBA, S.A.U). The insulated material is polyamide #12. Circular shape, sizes: 30, 40, 55, 65, 80 mm diameter. ○ Stainless steel conductive metal electrodes (AISI 304L)	○ Control unit (CPU) ○ Device bottom panel ○ Touchscreen displays with GUI ○ Outlets connectors for treatment handles and return electrode The IDC0409 Device accessories: • Smart Handle • Diathermia treatment electrodes with indicative thermal sensors imbedded in them: ○ Thin-layer insulated electrodes (called "Capacitive" or "CAP" electrodes by INDIBA S.A.U). The insulated material is polyamide #12.	○ Device bottom panel ○ Incorporated display screen ○ Outlets connectors for treatment handles and return electrode The Activ 902 Device accessories: • Handles • Diathermia treatment electrodes: ○ Thin-layer insulated electrodes (called "Capacitive" or "CAP" electrodes by INDIBA S.A.U). The insulated material is polyamide #12. Circular shape, sizes: 30, 40, 55, 65, 80 mm diameter. ○ Stainless steel conductive metal	○ Control unit (CPU) ○ Incorporated flip display screen ○ Touchscreen displays with GUI ○ Outlets connectors for treatment handles and return electrode The Activ CT9 Device accessories: • Diathermia treatment electrodes: ○ Thin-layer insulated electrodes (called "Capacitive" or "CAP" electrodes by INDIBA S.A.U). The insulated material is polyamide #12. Circular shape, sizes: 12, 19, 25, 30, 40,

	ELITE Predicate Device; INDIBA S.A.U K161458	**EVONY Device Subject device; INDIBA S.A.U**	**Activ 902 Predicate Device; INDIBA S.A.U K161458**	**Activ CT9 Device Subject device; INDIBA S.A.U**
	(called "Resistive" or "RES" electrodes by INDIBA S.A.U), circular shape, sizes: 35, 50, 65, 90 mm diameter. • Return electrode (plate) – stainless steel (AISI 304L) • Massager piece • IR thermometer • Conductive gel Other Components Included with Device: • Power Supply Cable • Electrode Case with Foam	Circular shape, sizes: 19, 30, 35, 40, 55, 65, 80 mm diameter and 35 mm diameter curved. ○ Stainless steel conductive metal electrodes (AISI 304L) (called "Resistive" or "RES" electrodes by INDIBA S.A.U), circular shape, sizes: 19, 35, 50, 65, 90 mm diameter. • Return electrode (plate) with indicative thermal sensors imbedded in it made of stainless steel (AISI 304L) • Sculpture electrodes • IR thermometer • Conductive gel	electrodes (AISI 304L) (called "Resistive" or "RES" electrodes by INDIBA S.A.U), circular shape, sizes: 35, 50, 65, 90 mm diameter. • Return electrode (plate) - stainless steel (AISI 304L) • Massager piece • IR thermometer • Conductive gel Other Components Included with Device: • Power Supply Cable • Electrode Case with Foam	55, 65, 80 mm diameter. ○ Stainless steel conductive metal electrodes (AISI 304L) (called "Resistive" or "RES" electrodes by INDIBA S.A.U), circular shape, sizes: 35, 50, 65, 90 mm diameter. • Return electrode (plate) - stainless steel (AISI 304L) • Massager piece • Fascia electrodes • Target electrodes • IR thermometer • Conductive gel Other Components Included with Device:

	ELITE Predicate Device; INDIBA S.A.U K161458	**EVONY Device Subject device; INDIBA S.A.U**	**Activ 902 Predicate Device; INDIBA S.A.U K161458**	**Activ CT9 Device Subject device; INDIBA S.A.U**
		Other Components Included with Device: • Power Supply Cable • Electrode Case with foam		• Power Supply Cable • Electrode Case with Foam
Input power	Input power: 220-240 VAC, 50-60 Hz	Input power: 100-240 VAC, 50-60 Hz	Input power: 220-240 VAC 50-60 Hz	Input power: 100-240 VAC, 50-60 Hz
Physical specifications	Dimensions: 458 mm W (width) x 440 mm D (depth) x 170 mm H (height) Weight: 14.1 kg	Cart Dimensions: 670 mm W (width) x 550 mm D (depth) x 1,370 mm H (height) Weight: 50 kg	Dimensions: 458 mm W (width) x 440 mm D (depth) x 170 mm H (height) Weight: 14.1 kg	Dimensions: 400 mm W (width) x 530 mm D (depth) x 150 mm H (height – with display folded) Weight: 8.6 kg
Output frequency in RES mode	448 kHz	Idem	448 kHz	Idem
Output frequency in CAP mode	400-449 kHz	448kHz	400-449 kHz	448kHz
Maximum output power in RES mode	200w	Idem	200w	Idem
Maximum output power in CAP mode	450 VA	Idem	450 VA	Idem
Maximal RF step in RES mode	1% (≥ 2 W)	1% (≥ 2 W)	1% (≥ 2 W)	0.2 - 4: 0.2% (≥ 0.4 W) 2 – 40: 2% (≥ 4 W) 5 – 100: 5% (≥ 10 W)

	ELITE Predicate Device; INDIBA S.A.U K161458	**EVONY Device Subject device; INDIBA S.A.U**	**Activ 902 Predicate Device; INDIBA S.A.U K161458**	**Activ CT9 Device Subject device; INDIBA S.A.U**
Maximal RF step in CAP mode	5%	1%	5%	0.2%
Display interface and dimensions	5.7" color TFT (320 x 240 pixels)	21.5" color TFT (1920 x 1080 pixels)	5.7" color TFT (320 x 240 pixels)	8" color TFT (800 x 480 pixels)
Timer range	0-99 minutes	0-90 minutes	0-99 minutes	0-99 minutes
Compatibility with Environment and Other Devices	The ELITE is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem	The Activ 902 is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem
Electrical Safety	Power Requirements: 220-240 VAC 50-60 Hz The ELITE Device is compliant with the IEC 60601-1 standard.	idem	Power Requirements: 220-240 VAC 50-60 Hz The Activ 902 Device is compliant with the IEC 60601-1 standard.	idem
Mechanical Safety	The ELITE is compliant with the IEC 60601-1 standard.	idem	The Activ 902 is compliant with the IEC 60601-1 standard.	idem
Thermal Safety	The ELITE is compliant with the IEC 60601-1 standard.	idem	The Activ 902 is compliant with the IEC 60601-1 standard.	idem
Radiation Safety	The ELITE is compliant with the IEC 60601-1-2 (EMC Safety) standard.	idem	The Activ 902 is compliant with the IEC 60601-1-2 (EMC Safety) standard.	idem
Biocompatibility	All of the device materials that come in direct contact with the human skin are biocompatible.	idem	All of the device materials that come in direct contact with the human skin are biocompatible.	idem

Comparison Discussion:

The INDIBA Diathermia Radiofrequency Activ device model (Activ CT9 device) and the INDIBA Diathermia Radiofrequency Deep Care device model (EVONY device) are portable, computerized, software-controlled device models comprising a console with a touchscreen, and equipped with several treatment handles and electrodes and intended for the purpose of elevating tissue temperature and provide a topical heating for treatment of selected medical conditions such as: relief of pain, muscle spasms and increase in local blood circulation.
The INDIBA Diathermia Radiofrequency Activ device model also comprises massage applicators intended to provide a temporary reduction in the appearance of cellulite by a mechanical massaging.

The indications for use and technological characteristics of the subject device models are substantially equivalent to the indications for use and technological characteristics of the predicate device models**.**

The subject device models are based on the same underlying RF technology as employed in the predicate device models. The mechanism of action and mechanism of operation are essentially identical to that of the predicate device models. The main modification in the subject device models do not raise new questions of safety or effectiveness therefore, the subject device models are substantially equivalent to the predicate device models.
The technological characteristics of the subject device models compared to the predicate device models do not raise new safety or effectiveness concerns. Furthermore, the subject device models underwent performance testing including software validation testing, electrical and mechanical safety testing, EMC testing, and specific bench testing, including RF output power testing.
All of the above-mentioned performance test protocols were designed and performed in the same manner as with the predicate device models and the test results demonstrated that the subject device models have successfully passed the tests and that all of the device requirements were fully met.

Conclusion:

Conclusively, the subject device models, the INDIBA Diathermia Radiofrequency Activ device model (Activ CT9 device) and the INDIBA Diathermia Radiofrequency Deep Care device model (EVONY device) are substantially equivalent to the predicate device models, the INDIBA Diathermia Radiofrequency Activ 902 device model and the INDIBA Diathermia Radiofrequency ELITE device model respectively, and therefore, may be legally marketed in the USA.