January 22, 2025

COMPEX, spol, s.r.o.
Rob Packard
Palackeho trida 924/105
Brno, 612 00
Czech Republic

Re: K240311
Trade/Device Name: JETT Medical II
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 13, 2024
Received: December 13, 2024

Dear Rob Packard:

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 08:10:04 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
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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)*

K240311

Device Name

JETT Medical II

Indications for Use *(Describe)*

JETT Medical II is intended for non-ablative treatment of mild to moderate facial wrinkles and rhytids for skin phototypes I-IV.

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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K240311

510(k) SUMMARY

I. SUBMITTER INFORMATION - 807.92(a)(1)

Name: COMPEX, spol. s r.o.
Adress: Palackeho trida 924/105, Brno, Czech Republic
Postal code: 612 00

Contact Person: Rob Packard
Date Prepared: January 21, 2025

II. DEVICE - 807.92(a)(2)

Name of Device:	JETT Medical II
Classification Name:	Electrosurgical Cutting & Coagulation Device
Regulation:	21 CFR §878.4400
Regulatory Class:	Class II
Product Classification Code:	GEI

III. PREDICATE DEVICE - 807.92(a)(3)

Predicate Manufacturer:	Ellman International
Predicate Trade Name:	Pelleve GlideSafe Non-Ablative Wrinkle Treatment System
Predicate 510(k):	K102698
Classification Name:	Electrosurgical Cutting & Coagulation Device
Regulation:	21 CFR §878.4400
Regulatory Class:	Class II
Product Classification Code:	GEI

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION - 807.92(a)(4)

JETT Medical II is a portable medical device designed for non-ablative treatment of wrinkles and rhytids. The device works on the physical principle of a sequence of DC microcurrents, which are generated by electrically or battery powered generator and that are transmited to the patient skin through indifferent conductive gel. Patient loop is formed by pairing the handpiece with one of flat applicators with the grounding electrode (cylinder or disposable).

Device consists of the standard package and optional accessories:

Standard package
• The device itself (dimensions: 275 x 100 x 183 mm) contains Generator and control console
• Pen III
• Flat applicator 3 mm
• Flat applicator 5 mm
• Flat applicator 10 mm
• Flat applicator 20 mm
• Cylinder electrode
• Cylinder electrode 30 mm

• Disposable electrode
• Curly connection cable for disposable electrodes
• Connection cable for cylinder electrode
• Extension cable for power supply
• Power supply unit
• Foot switch
• Rechargeable battery
Optional accessories
• Pen III/S
• Flat applicator 3 mm S
• Flat applicator 5 mm S
• Flat applicator 10 mm S
• Flat applicator 20 mm S

V. INTENDED USE/INDICATIONS FOR USE - 807.92(a)(5)

JETT Medical II is intended for non-ablative treatment of mild to moderate facial wrinkles and rhytids for skin phototypes I-IV.

VI. TECHNOLOGICAL COMPARISON - 807.92(a)(6)

Comparison of the JETT Medical II and the predicate device shows the technological characteristics of the subject device and currently marketed predicate device. The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

Comparison of all characteristics is given in the following table.

	JETT Medical II	**Pelleve GlideSafe Non-Ablative Wrinkle Treatment System (K102698)**	**Comparison**
Regulation name	Electrosurgical, cutting and coagulation device and accessories	Electrosurgical, cutting and coagulation device and accessories	Identical
Regulation number	21 CFR 878.4400	21 CFR 878.4400	Identical
Regulatory Class	II	II	Identical
Product Code	GEI	GEI	Identical
Rx/OTC	Prescription	Prescription	Identical
Indications for Use	JETT Medical II is intended for non-ablative treatment of mild to moderate facial wrinkles and rhytids for skin phototypes I-IV.	Non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin phototypes I-IV.	Identical
Principle of operation	Application of heat to the tissue by DC current.	Application of heat to the tissue with RF energy.	Identical
Interface	Touch screen user applied interface to program and set the controls for the patient application; there are hand-pieces utilized to deliver the treatment.	Buttons and knobs on the unit; there is a hand-piece utilized to deliver the treatment.	Similar.

Treatment	Non-ablative	Non-ablative	Identical
Energy type	Direct current (DC)	Alternating current (AC) with 4MHz (radiofrequency)	Different, but difference has no influence on intended use - thermal effects on tissue are identical which does not introduce new questions of safety and effectiveness (Refer to Vol 18_Bench Substantial Equivalence Test for difference in Energy source). Safety of subject device is supported by Electrical safety and EMC according to IEC 60601-1, IEC 60601-1-2
Modality	Monopolar	Monopolar, bipolar	Identical, monopolar modality of predicate is used for our intended use
Device Activation	Using footswitch	Using a hand or footswitch based on user preference	Similar
Treatment Modes	Multiple treatment levels	Multiple treatment levels	Identical
Supply Power Input	100-240 V 47-63 Hz	110-250 V 50/60 Hz	Similar, supply power input of the subject device is covered by the predicate which does not introduce new questions of safety and effectiveness. Safety of subject device is supported by Electrical safety and EMC according to IEC 60601-1, IEC 60601-1-2
Output Frequency	N/A	4 MHz	Different, because subject device uses DC, while predicate uses AC. The difference has no influence on principle of operation which does not introduce new questions of safety and effectiveness. Safety of subject device is supported by Electrical safety and EMC according to IEC 60601-1, IEC 60601-1-2
Max. Power Output	4.4 W	120 W	Different, max power output of the subject device is covered by the predicate. Predicate has wider use, but performance for non-ablative treatment is comparable to performance of subject device which does not introduce new questions of safety and effectiveness. Safety of subject device is supported by Electrical safety and EMC according to IEC 60601-1, IEC 60601-1-2
Operating Temperature	5°C to 40°C	10°C to 40°C	Similar. Operating temperature mostly overlaps with predicate device.
Operating Humidity	30-70%	30-75%	Similar

Treatment temperature Range	< 42°C	39°C to 42°C	Similar
Power Level Adjustable via Applicator	No, Via central console.	No, Via central console.	Similar
System Components	System consists of electrosurgical unit with generator and control console, handpieces, flat applicators, cables, grounding electrodes, power supply, footswitch and rechargeable battery.	Rf generator, handpieces, footswitch, fingerswitch, cables, neutral plates, disposable electrodes,	Different, but difference has no influence on intended use. For treatment only handpieces with applicator are use which does not introduce new questions of safety and effectiveness. Safety of subject device is supported by Electrical safety and EMC according to IEC 60601-1, IEC 60601-1-2, biocompatibility according to 10993-1 and tissue testing
Handpiece	Pen III Pen III/S	GlideSafe™ Handpiece	Similar, the Pen of the subject device is similar as Handpiece of predicate – deliver energy from generator to the patient´s skin which does not introduce new questions of safety and effectiveness
Neutral electrode	Yes	Yes	Identical
Material of Neutral Electrode	Cylinder electrode (reusable): aluminum alloy Hurev electrode (disposable): Protective Liner (Polyethylene terephthalate), Hydrogel, Conductive Film (Carbon), Backing Material (Polyester non-woven fabric), Sensor (Ag/AgCl coated 20% glass-filled ABS), Snap (SUS304), Leadwire (PVC jacket Carbon wire)	The effective electrodes are two aluminum oil conductors, covered by a hydrogel conductive adhesive (disposable)	Different, but difference in neutral electrodes does not affect the patient connection for the treatment which does not introduce new questions of safety and effectiveness. Safety is supported by biocompatibility according to ISO 10993-1
Applicator	Yes (reusable)	Yes (reusable) - inseparable part of handpiece	Identical
Applicator material	aluminum alloy	Gold-plated brass	Different, but difference has no influence on intended use, because emitting energy from applicator to tissues which does not introduce new questions of safety and effectiveness. Moreover, applicator is sterilized before first and after each treatment. Safety is supported by biocompatibility according to ISO 10993-1
Size in diameters	applicators with diameter 3/5/10/20 mm	Applicators with diameter 7.5/10/15/20 mm	Similar, size is covered by predicate

Applicator Weight with pen	<100g	<100g	Identical
System Dimensions	27.5 x 12.5 x 18.5 cm	24cm x18cm x 42cm	Similar
System weight	Approx. 1.7 kg	26 lb (11.8 kg)	Subject device weighs much lighter than predicate, which makes it easier to carry if necessary.
Sterilization	Steam sterilization (at 134°C for 3 min, drying time is 27 min)	N/A	Different, but difference has no influence on intended use which does not introduce new questions of safety and effectiveness. Sterilization is performed according to validated procedure (SAL= 10^{-6}) stated in the Instruction of use.
Performance Testing	Complies with IEC 60601-1, IEC 60601-1-2	Complies with IEC 60601-1, IEC 60601-1-2	Identical

VII. NON-CLINICAL TESTING - 807.92(b)(1)

Verification/validation activities from non-clinical testing as described below demonstrate that the differences do not raise any new issues of safety or effectiveness of the JETT Medical II compared to the predicate device. Non-clinical testing has demonstrated that the JETT Medical II complies with standards and requirements and it is substantially equivalent to the predicate device.

Electrical safety and electromagnetic compatibility (EMC)

The JETT Medical II electrical safety and electromagnetic compatibility has been evaluated and found to be in compliance with:

- IEC 60601-1:2005 + A1:2012 + A11:2011 + A12:2014 + AC:2014-07+COR3:2022, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbance Requirements and tests
- 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 60601-1-6:2010 + A1:2015+AMD2:2020, Medical electrical equipment - Part 1- 6: General requirements for basic safety and essential performance - Collateral standard: Usability

Software

The JETT Medical II software testing was performed and found to be in compliance with:

- FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
- IEC 62304 Ed. 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life-cycle processes

Biocompatibility

The patient-contacting components of the device are flat applicators and cylinder electrode and the biocompatibility of these components comply with:

- FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

- ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within risk management process.
- 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 irritation and delayed-type hypersensitivity

Sterilization

Sterilization of the patient-contacting components of the device (flat applicators) of JETT Medical II has been found to be in compliance with:

- ISO 17665-1:2006, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Risk management

Risk analysis for JETT Medical II has been evaluated and found to comply with:

- ISO 14971:2019 Medical devices – Application of risk management to medical devices

Usability

The JETT Medical II usability has been evaluated and found to comply with:

- FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices
- IEC 62366-1:2015+AMD1:2020Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
- IEC 60601-1-6:2010 + A1:2015+AMD2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Bench testing - Skin temperature during treatment

Bench test was performed to ensure that the JETT Medical II performs as intended and meets design specifications.

The results showed that the temperature rise is quite well provable as after the application of the device at different intensities the temperature of skin was higher than the initial temperature. The temperature also rose with higher intensities. The increase was in almost all cases linear.

The highest temperature of 41.3 was measured at the highest intensity with a flat applicator 20 mm. The temperature never increased above 42°C.

Based on these results we can state that the device in its normal function and while adhering to treatment protocols is safe for the patient.

Substantial Equivalence - Test to assess differences in Energy source between subject device and predicate device

The energy source of the subject device is different from the predicate device (DC vs AC with radiofrequency). As is the supply power output, output frequency, max. output power). A substantial equivalence test was conducted to demonstrate that the thermal effect of DC and RF is the same. The substantial equivalence test showed that the subject device is at least, as safe and equally efficient to the predicate device, that at similar intensity settings the delivered energy is similar to that of the predicate. Therefore this technological difference does not raise new questions of safety or effectiveness.

Animal testing

No animal test was performed.

VIII. CLINICAL TESTING - 807.92(b)(2)

A prospective, multi-center, non-randomized, evaluator-blinded study was provided as clinical evidence of the safety and effectiveness of the device. The clinical evidence was presented as a single-arm analysis for the JPM II test treatment group (RRTST). The study population consists of subjects who have wrinkles mild to moderate in severity as specified by the Fitzpatrick wrinkle classification system (FWCS) with Fitzpatrick skin scale I-IV. The primary effectiveness endpoint is defined as an improvement of ≥ 1 point on the FWCS from baseline at the 3-month follow-up after the last treatment. The lower bound of 95% confidence interval of the response rate in the JPM II test treatment group (RRTST) is greater than the pre-defined threshold of 0.75.

IX. Conclusion - 807.92(b)(3)

The subject device JETT Medical II has the same intended use/indication for use. Despite the technological differences, non-clinical and clinical tests have shown that JETT Medical II is substantially equivalent in terms of safety and effectiveness to the predicate device and the differences do not raise any new or different questions of safety and effectiveness.