February 25, 2021

Novoxel Ltd.
% Janice Hogan
Partner
Hogan Lovells, US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K202988
Trade/Device Name: Tixel System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 28, 2021
Received: January 28, 2021

Dear Janice Hogan:

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,

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: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*
K202988

Device Name

Tixel® System

Indications for Use *(Describe)*

The Tixel® System is intended for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
Novoxel's Tixel® System
K202988

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Novoxel, Ltd.
43 Hamelaha Street
Netanya, Israel 4250573
Phone: + 972 9 7739074
Facsimile: +972 9 793 9953
Contact Person: Ronen Shavit, CTO

Date Prepared:

February 24, 2021

Name of Device

Tixel® System

Common or Usual Name

Thermo-mechanical fractional skin treatment device

Classification Name

21 CFR 878.4400, Class II, Product Code: GEI

Predicate Devices

Venus Concept USA Ltd., Venus Viva SR Device (K150161) (Predicate Device)

CONMED Altrus® Thermal Tissue Fusion System (K101534) (Reference device)

Intended Use / Indications for Use

The Tixel® System is intended for dermatological procedures requiring ablation and resurfacing of the skin.

Device Description

The Tixel is a thermo-mechanical fractional skin treatment device that is designed to perform ablative fractional skin treatments. The treatment is achieved by transfer of energy in the form of heat to the skin to create coagulation sites.

The treatment is applied through an operating Tip that consists of 81 (standard tip) or 24 (small tip) biocompatible titanium square pyramidal shape assembled over gold plated copper base that are heated by an underlying flat ceramic heating element. The desired skin treatment is achieved by defining the speed and distance at which the Tip contacts and pushes the skin and the amount of pulses performed. Based on the treatment parameters selected the pyramids contact the skin surface in 81 (or 24 for small tip) discrete, non-overlapping areas and by the transfer of heat, a matrix of coagulation sites and thermal necrosis is generated.

Tixel transfers heat to the tissue by direct conduction to target tissue in a localized manner via the discrete non-overlapping pyramids. The Tixel Tip contacts the skin for a very short period, defined by pulse duration that varies between 5 and 16ms.

The Tip is mounted directly above the heating element in the Handpiece. The Tip and the heating element are mounted on a titanium alloy assembly. The Tip assembly structure is rigidly connected to the motor shaft (also known as forcer) by a polymer component. The polymeric components provide both thermal and electrical insulation between the heating element and the motor shaft. The Handpiece is attached to the Tixel Console by an umbilical tube. The console touch screen is used to control the system parameters.

Technological Characteristics

Both the Tixel and its predicate device transfer energy through a handpiece attached to a system console, where the output is controlled by the clinician operating the device to achieve the desired effect. The tips of the Tixel and the predicate device are comparable in physical design, i.e., they consist of a geometrical array of pins or pyramids. The size of the tip is comparable between the two devices. All patient contacting materials for both the subject and predicate device have been found to be biocompatible. The Tixel and its predicate device deliver non-invasive fractional skin treatments through similar methods of application (handpiece/Tip applied to the area with treatment parameters controlled through the console). For both devices, pulses are delivered to the target location using an array of pins or pyramids.

The predicate device utilizes fractional radiofrequency pulses emitted from the tip to achieve thermolysis, whereas the Tixel delivers fractional thermal energy through heat conduction. This difference does not result in different types of safety or effectiveness questions because the same key questions are raised by both methods of energy application. Both devices are intended to deliver a localized thermal effect with limited heat delivered to adjacent tissue, in a fractional pattern. Both energy delivery methods result in local heating of the skin to cause thermally induced tissue coagulation and ablation.

In addition, using metallic elements to deliver thermal energy has been previously cleared for other electrosurgical cutting and coagulation devices, such as the CONMED Altrus® reference device. For both the Tixel and the CONMED Altrus, the energy is delivered to the handpiece and increases the temperature of the heating elements by means of resistive heating.

Biocompatibility

The Tixel is intended for treatment of soft tissue and dermal application (e.g., skin resurfacing treatment). The only patient contacting components of the Tixel include the tip and the handle. According to ISO-10993-1 Biological Evaluation of Medical Devices, and the FDA's Biocompatibility Guidance, Tixel is a surface device ($\leqslant$ 24 hours contact duration) in contact with skin. Therefore, cytotoxicity, sensitization, and irritation testing have been conducted. All tests showed passing results. In addition, surface chemical analysis was performed to assess for residue buildup or chemical change over a lifetime of use. The results showed that no diffusion of the underlying materials could be detected.

Cleaning/Disinfection/Shelf life

The Tixel is a reusable device. The user is required to clean and disinfect the device after each use. The Tip undergoes high level disinfection in accordance with ISO 20857 via dry heat, which has been shown to achieve complete kill of at least 10^6 *Bacillus atrophaeus* spores. Cleaning validation has been conducted in accordance with ASTM F3208-18: Standard Guide

for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices, and was successfully passed.

The Tixel is designed to limit the number of pulses per a single Tip to 100,000 pulses. The number of pulses for each handpiece is stored in the handpiece controller. Shelf life testing following real life operation showed that there was no evidence of deterioration of the handpieces following 250,000 cycles.

Performance Data

Electrical safety and electromagnetic compatibility (EMC) testing for Tixel was conducted by an independent test laboratory in accordance with IEC 60601-1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance and IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

Software verification testing was conducted, and the testing results were found acceptable for software release.

Bench testing demonstrated that Tixel performs according to specifications and functions as intended.

Animal Study

An in vivo study using a porcine model was conducted to evaluate performance of the Tixel device in comparison to the predicate Venus Viva device. The study comprised five female domestic pigs, each subjected to multiple topical exposures of fractional thermal pulses via Tixel or fractional radiofrequency via the predicate device, at different treatment settings (Low, Medium, and High). Macroscopic evaluation of the activation sites was performed, and the activation sites were harvested at the end of the 14-days study period. Harvested samples were processed histologically and evaluated for depth and width of the lesions, inflammatory reaction, and healing process (i.e. edema, necrosis, hemorrhage and polynuclear infiltration).

Tixel-treated and predicate-treated animals demonstrated similar immediate skin changes. Histopathology demonstrated that the Tixel created a focus of ablation over a wedge-shaped dermal area of collagen coagulation. Data analysis showed increased energy levels led to proportionately greater thermal lesions. The average thermal lesion depth of the Tixel was similar to the Venus Viva predicate at the medium and high settings, indicating the similarity of the treatment effects.

Taken together, the animal study results show that the Tixel displays a similar treatment effect compared to the predicate.

Conclusions

The Tixel has the same intended use, technological characteristics, and principles of operation as its predicate device. The technological differences between the Tixel and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the differences in technological characteristics compared to the predicate do not adversely impact performance. Therefore, the Tixel is substantially equivalent to its predicate device.