June 21, 2023

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

Re: K223033
Trade/Device Name: Tixel® 2 System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 25, 2023
Received: May 25, 2023

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.21 13:17:13 -04'00'

Mark Trumbore, 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)*

K223033

Device Name
Tixel® 2 System

Indications for Use *(Describe)*
The Tixel® 2 System is intended for dermatological procedures requiring ablation and resurfacing of the skin, and for treatment of periorbital wrinkles.

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

Novoxel's Tixel® 2 System

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

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Contact Person: Omri Findler, Dir. Clin. QA/RA

Date Prepared

June 19th, 2023

Name of Device

Tixel® 2 System

Common or Usual Name

Thermo-mechanical fractional skin treatment device

Classification Name

21 CFR 878.4400, Class II, Product Code: GEI

Predicate Device

Novoxel Tixel® System (K202988)

Intended Use / Indications for Use

The Tixel® 2 System is intended for dermatological procedures requiring ablation and resurfacing of the skin, and for treatment of periorbital wrinkles.

Device Description

The Tixel® 2 System 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 shapes assembled over a 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 number of pulses performed. Based on the

treatment parameters selected, the pyramids contact the skin surface in 81 (or 24 for the small Tip) discrete, non-overlapping areas and by the transfer of heat, a matrix of coagulation sites and thermal necrosis is generated.

Tixel 2 transfers heat to the tissue by direct conduction to target tissue in a localized manner via the discrete non-overlapping pyramids. The complete Tixel 2 System contains two Handpieces, which are attached to the Tixel 2 Console by an umbilical tube. The Console's touch screen is used to control the system parameters.

Technological Characteristics

The Tixel 2 enables connection of up to two Handpieces in comparison to the Tixel, which connects to only one. Both the Tixel 2 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 2 and the predicate device are identical in all aspects. All patient contacting materials for both the Tixel 2 and the predicate device are identical in all aspects and biocompatible. The Tixel 2 and its predicate device deliver non-invasive fractional skin treatments through the exact same method of application (same Handpiece and same Tip design applied to the area with identical treatment parameters controlled through the console).

<u>The following differences exist between the subject and predicate devices:</u>

- Addition of periorbital use
- Up to two Handpieces can be plugged to the Tixel 2 in comparison to one in Tixel
- Increase in air blower capacity
- Tip and HP use-life extended
- Upgrade to the Graphic User Interface (GUI)
- Change in external casing design
- Shorter disinfection time
- Addition of repeat pulse mode
- Improvement to displayed Tip temperature during cooling

The differences between the devices do not result in different types of safety or effectiveness questions because the delivered treatment is unchanged. Both devices are intended to deliver a fractional thermal treatment with limited heat delivered to adjacent tissue. The energy transfer results in local heating of the skin to cause thermally induced tissue coagulation and ablation.

Performance Data

The following tests were performed to establish equivalence:

- Disinfection validation per ISO 20857
- Use-life validation testing
- Software and cybersecurity validation per FDA guidance
- Electrical safety per IEC 60601-1 and 60601-1-6
- EMC per IEC 60601-1-2
- Comparative animal tissue histology studies (In-Vivo and Ex-Vivo)

Clinical Data

A prospective, blinded (pre- and post-treatment), single-arm clinical study was performed in two clinics (US, Israel). The study is designed to evaluate the safety and efficacy of the Tixel 2 in treatment of periorbital wrinkles and was conducted with 51 patients**.** Forty-eight patients have completed the study. Analgesic materials were not applied; only forced air cooling was used.

The results support the safety of the device when used for periorbital wrinkle treatment. No SAEs or significant related AEs were noted. 2 AEs were reported in two (n=2) subjects (3.92%): Erythema (probably related, resolved within two days) and back pain (unrelated). In both events, medications were administered to treat the event.

FWCS score was performed by blinded raters for baseline and the three months follow up visits and demonstrated improvement > 1 grade. GAIS assessment was performed at the follow up visit compared to baseline. The mean score at Visit 5 (1st follow up) was 3.54±0.68. The mean score remained almost the same, 3.52±0.58 at Visit 6 (3-month FU). Most of the subjects achieved the highest improvement grade (grade 4, 75-100 %). At least 2 out of the 3 raters were in agreement for grading 83.3% of subjects as responders.

Mean procedure-associated VAS pain scores reported by the subjects at all treatment visits were low.

Conclusions: Patient comfort, satisfaction, safety, and the efficacy of the Tixel 2 in the treatment of periorbital wrinkles have been adequately demonstrated.

Conclusions

The Tixel 2 has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Tixel 2 and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Tixel 2 is as safe and effective as the predicate device. Therefore, the Tixel 2 is substantially equivalent to its predicate device.