510(k) SUMMARY

Novoxel's Tixel® 2 System

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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.