

June 2, 2022

Re: 510(k) Clearance of the Renuvion[®] Dermal Handpiece, APYX-044-DERM

Dear Physician,

Apyx Medical is pleased to announce the FDA 510(k) clearance (K211652) of the new **Renuvion[®] Dermal Handpiece**. This handpiece is intended for dermatological procedures for the treatment of moderate to severe wrinkles and rhytides, limited to patients with Fitzpatrick Skin Types I, II or III. The treatment, branded “Facial Renewal”, is achieved through controlled heating of the outer layers of the skin so that part or all the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis.



On March 14, 2022, the U.S. FDA issued a Medical Device Safety Communication to warn “against the use of the Renuvion/J-Plasma devices for procedures intended to improve the appearance of the skin through dermal resurfacing (a procedure on the skin to treat wrinkles)” because, at that time, the use of these devices had not been determined to be safe or effective for any specific procedure intended to improve the appearance of skin. With this 510(k) clearance, the Apyx Medical **Renuvion Dermal Handpiece** has been determined to be safe and effective specifically for improving the appearance of moderate to severe wrinkles and rhytides in patients with Fitzpatrick skin types I, II and III. At this time, it has not been determined to be safe or effective for other skin types or other procedures that improve the appearance of the skin such as reducing the appearance of scars, and no Apyx Medical handpiece has been cleared for skin contraction.

The handpiece will be available shortly, and, as with Apyx Medical’s other products, its initial sale will include a training program that will be delivered by our clinical nursing staff. The **instructions for use** (eIFU) for the **Renuvion Dermal Handpiece**, including safety information, can be found on our website here: <https://eifu.apyxmedical.com/apyxmedical/en/handpieces?keycode=apyxmedical0000033> .

We look forward to working with you to provide a new treatment to your patients. Please reach out to your Apyx Medical representative with any questions—our team is here to support you and your patients.

Sincerely,

Charlie Goodwin
President and CEO

Todd Hornsby
Executive Vice President