



July 21, 2022

Recent 510(k) Clearances of the **Renuvion® Dermal Handpiece** for the treatment of moderate to severe wrinkles and rhytides, and **Renuvion APR Handpieces** for improving lax (loose skin) in the neck and submental region

Dear Physician,

Apyx Medical is pleased to announce on July 15, 2022, we received a new FDA 510(k) clearance (K220970) for the **Renuvion® APR Handpieces**. In addition to being used for cutting, coagulation and ablation of soft tissue during open surgical procedures, the **Renuvion APR handpieces** are now indicated for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.

On March 14, 2022, the U.S. FDA issued a Medical Device Safety Communication warning 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) or to improve the appearance of the skin through “skin contraction” because, at that time, the use of our devices had not yet been determined to be safe and effective for any specific procedure intended to improve the appearance of skin. Since the issuance of the safety communication, Apyx has received two new clearances for specific procedures intended to improve the appearance of skin. On May 26, 2022, the **Renuvion Dermal Handpiece received 510(k) clearance** for dermatological procedures for the treatment of moderate to severe wrinkles and rhytides, limited to patients with Fitzpatrick Skin Types I, II or III. On July 15, 2022, the **Renuvion APR Handpieces received 510(k) clearance for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.**

The **Renuvion Dermal Handpiece** is the only Renuvion handpiece intended for dermal resurfacing; do not use the **Renuvion APR Handpieces** for dermal resurfacing or any non-surgical, skin/ dermal, or topical uses.

The **Renuvion Handpieces** have not been cleared or approved for use with liposuction. Currently there are **no** subdermal RF heating devices (invasive or minimally invasive) that have been cleared for use in aesthetic procedures in combination with liposuction.

Apyx Medical will provide required training by our clinical nursing staff to users for the **Renuvion Dermal Handpiece** and for the new intended use for the **Renuvion APR handpieces**. The instructions for use (eIFU) for the Renuvion Dermal Handpiece and the updated **instructions for use (eIFU)** for the **Renuvion Dermal Handpiece** and the **Renuvion APR Handpieces**, including safety information, can be found on our website here: <https://eifu.apyxmedical.com/apyxmedical/en>



We are excited to make the **Renuvion APR Handpiece** available to surgeons and patients seeking a new, clinically-proven treatment option to improve the appearance of lax skin in the neck and submental region. Please reach out to your Apyx Medical representative with any questions—our team is here to support you. We look forward to working with you to provide a new treatment to your patients.

Sincerely,

Charlie Goodwin  
President and CEO

Todd Hornsby  
Executive Vice President