Safety and Efficacy of Sofwave™ Treatment to Lift Upper Arm Lax Skin

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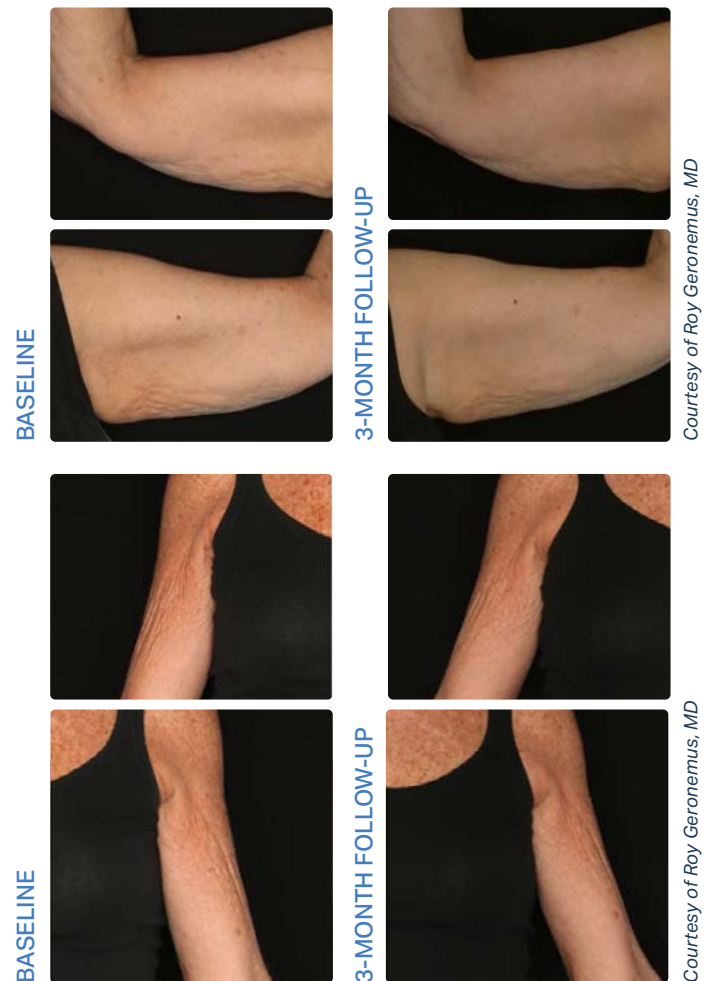**Dr. Amy Taub**
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INDICATIONS: Improvement the appearance of upper arms lax skin

STUDY TYPE: Pivotal - submitted to the FDA (K233104): *"The SofWave System is indicated to improve the appearance of skin laxity on the upper arms."*

NUMBER OF SUBJECTS: 46 subjects

RESULTS: 46 subjects were treated on both upper arms (a total of 92 treated areas). Subjects attended 2 treatment sessions (1-3 weeks apart), and a follow-up visit 3 months after the final treatment visit. The primary efficacy evaluation found that 93% of treated arms showed improvement in upper arm skin laxity, as assessed by the correct identification of the pre- and post-treatment photographs by at least 2 of 3 blinded reviewers. Consistent with the results for the primary efficacy endpoint, the secondary efficacy endpoint results also supported device effectiveness for the expanded indications for use. As assessed by the blinded reviewers, on average the treated arms improved from severe skin laxity at baseline to moderate skin laxity after treatment, based on a 5-point upper arm skin crepiness/laxity grading scale. Additionally, 93% of the treated arms were improved or very much improved in appearance,

as rated by the blinded reviewers using the Global Aesthetic Improvement Scale. The clinical study also demonstrated a favorable safety profile for the SofWave System for use in improving the appearance of skin laxity on the upper arms. Throughout the study, there were no device-related adverse events. Anticipated tissue responses mostly consisted of erythema and edema that resolved spontaneously after treatment. Most subjects reported none to mild levels of pain during treatment and no discomfort afterward, further confirming that the device was well tolerated.

BASELINE

3-MONTH FOLLOW-UP

Courtesy of Roy Geronemus, MD

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