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Hologic receives FDA 510(k) clearance to market SculpSure® for non-invasive body contouring

Patients in Clinical Studies Report 100% Satisfaction Rate

Hologic, Inc. (Nasdaq: HOLX) has announced that the U.S. Food and Drug Administration (FDA) has granted an expanded FDA 510(k) clearance for Cynosure's non-invasive body contouring product, SculpSure®. The state-of-the-art body contouring laser treatment is now cleared to treat a double chin (also known as the submental area), marking the product's sixth cleared body treatment area. SculpSure® is also cleared to treat the abdomen, love handles (flanks), back, and inner and outer thighs.

"Most patients in the 57-person clinical trial received two brief treatments six weeks apart," said Dr. Lawrence Bass, board certified plastic surgeon and a principal investigator in the SculpSure clinical trials. "The short treatment time, 100% satisfaction rate, and dramatic contour reductions typically seen in the study patients give SculpSure the edge as the treatment of choice for the submental area."

SculpSure® is an advanced, non-invasive body contouring treatment that helps patients achieve a natural-looking, slimmer appearance. The fully customizable treatment uses a laser to raise the temperature of body fat to precisely disrupt and destroy fat cells under the skin. The fat cells are then naturally eliminated over time and do not return. Each treatment lasts approximately 25 minutes and requires no surgery or downtime.

"We are encouraged that our chin treatment was proven effective on patients with a body mass index (BMI) up to 43, while our competition in the non-invasive arena is only FDA-cleared to treat patients with a BMI up to 30," said Kevin Thornal, Divisional President of Cynosure at Hologic. "We are excited to provide our customers with a competitive advantage that can further widen their patient communities."

To learn more about SculpSure, please visit www.SculpSure.com.

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