EON SAFETY & EFFICACY VALIDATION STUDY

OBJECTIVE:

The objective of this study was to compare the safety and efficacy of EON to a predicate device (already FDA cleared), so that EON would be found to be substantially equivalent and receive FDA clearance via a 510(k).

METHODS:

A 36 patient, 3 site, abdominal subcutaneous adipose tissue reduction study was initiated in December 2018. The three sites were:

- Suzanne Kilmer, M.D. – Sacramento, CA,
- Jill Waibel, M.D. – Miami, FL and
- Thomas Fiala, M.D. – Altamonte Springs, FL.

The study evaluated:

- Before and after photos by blinded experts
- Circumferential measurements of the abdomen
- Ultrasound measurements for fat thickness
- Subject Satisfaction
- Adverse Events

Results:

Study	Predicate 2017 FDA Study	Dominion 2018 FDA Study
Sample Size	35	36
Treatment Time	25 minutes	15 minutes
Week 12 Mean Fat Reduction	-2.65 mm	-3.4 mm
Percentage of Fat Reduction	-11.5%	-15.1%
Subject Satisfaction	83%	89%
% Subjects with Nodules	23% (8/35)	11.1% (4/36)

CONCLUSION:

EON was found to be safe and effective and received FDA clearance on June 12, 2019.
EON could treat the entire abdomen in 1 hour.
EON had significantly greater fat reduction in a shorter period of time with less than half of the nodules than the predicate device.