Medical CE & FDA Technical Compliance Register: Liposonix Ultrasonic Weight Loss System

MEDICAL CE & FDA TECHNICAL COMPLIANCE REGISTER: LIPOSONIX ULTRASONIC WEIGHT LOSS SYSTEM

DEVICE IDENTIFICATION & CLASSIFICATION

The Liposonix Ultrasonic Weight Loss System is a non-invasive, high-intensity focused ultrasound (HIFU) device indicated for circumferential reduction of the abdomen and flanks (love handles). Operating at a nominal frequency of 2.0 MHz ± 5%, the system delivers targeted thermal coagulation zones (TCZs) at precise depths of 1.3 cm to 1.8 cm beneath the dermal layer, permanently destroying subcutaneous adipose tissue via thermal apoptosis.

INTERNAL HARDWARE TOPOLOGY & HIFU TRANSDUCER ARCHITECTURE

The system integrates a ceramic piezoelectric transducer encapsulated within a water-circulating handpiece assembly. Key subsystems include:

- RF driver board (200W peak output)
- Real-time impedance matching network
- Integrated thermistor array (5 sensing points)
- Closed-loop degassed water circulation pump
- 15-inch capacitive touchscreen control unit

The transducer generates a focal zone of 1.6 mm (width) by 16 mm (length) at f=45 mm, achieving acoustic intensities of 1,000 to 2,500 W/cm² spatial-peak temporal-average (Ispta).

EPIDERMAL PROTECTION MECHANISMS

To prevent superficial thermal injury, the Liposonix platform employs a contact-cooled sapphire window maintained at 10°C ± 2°C via integrated Peltier thermoelectric modules. Cutoff criteria include: skin temperature exceeding 42°C triggers automatic energy reduction; real-time impedance changes >20% abort the pulse.

TREATMENT ADVANTAGES & CLINICAL OUTCOMES

- Single-session treatment (60-90 minutes)

- Mean waist circumference reduction: 3.8 cm (1.5 inches) at 12 weeks post-treatment ($p < 0.001$)

- Patient satisfaction rate (Global Aesthetic Improvement Scale): 83% at 6 months

- Histological confirmation of adipocyte destruction without adjacent tissue damage

SPECIFICATION MATRIX

Parameter	**Specification**
Acoustic Frequency	2.0 MHz ± 5%
Focal Length	45 mm (fixed)
Focal Zone Dimensions	1.6 mm (width) x 16 mm (length)
Peak Acoustic Intensity (Ispta)	1,000 – 2,500 W/cm²
Pulse Energy	80 – 100 J (user-selectable)
Cooling System	Sapphire window + TEC + degassed water circulation
Skin Temperature Cutoff	42°C
Treatment Depth	1.3 – 1.8 cm subcutaneous

Power Supply	100-240 VAC, 50/60 Hz, 800 VA
Dimensions (Control Unit)	48 cm W x 50 cm D x 120 cm H
Weight	38 kg (84 lbs)
Display	15-inch capacitive touchscreen

REGULATORY COMPLIANCE & CERTIFICATIONS

The Liposonix system holds the following regulatory clearances:

- FDA 510(k) K112050 (Indication: Non-invasive circumferential reduction)
- CE Mark (Class IIb) under MDD 93/42/EEC, valid through MDR transition
- ISO 13485:2016 certified manufacturing facility
- IEC 60601-1 (Medical electrical equipment safety)
- IEC 60601-2-62 (Particular requirements for HIFU equipment)
- RoHS 3 (EU 2015/863) compliant
- Korea MFDS, Brazil ANVISA, and Canada Health license active

CLINICAL PROTOCOLS & TREATMENT PARAMETER REGISTER

Mandatory pre-treatment mapping: Use 3D calipers to measure subcutaneous fat thickness (minimum 2.5 cm required). Standard treatment parameters:

- Energy per pulse: 80-100 J
- Pulse repetition frequency: 0.5 Hz
- Total pulses per site: 300-400 (adjusted to treatment grid)
- Treatment grid: 1 cm spacing between adjacent pulse sites
- Maximum cumulative energy per session: 40 kJ

Contraindications include pregnancy, implanted electronic devices (pacemakers), hernias, and systemic anticoagulation therapy.