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ASIA EDITION

Wontech receives FDA clearance for HairBoom Air

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This is the second FDA clearance for hair loss medical devices

WONTECH, a leading Korean laser and energy based medical aesthetic device company announced that its LLLT hair loss treatment device, HairBoom Air, received U.S. Food and Drug Administration 510(K) clearance.

The U.S. Food and Drug Administration has cleared the HairBoom Air as a Class II for hair treatment medical device. This is the second FDA clearance for hair loss medical devices since the FDA cleared 'HairBoom' in 2018, and the 'HairBoom Air' is a U.S. market-friendly model for hair loss medical devices known in Korea as 'HairBoom' and 'HairBoom Air'. While many medical devices for hair loss treatment are composed of LD (Laser Diode) and LED terminal combinations, HairBoom Air, which was cleared by the U.S. FDA, has 69 LD terminals.

HairBoom Air is the latest model of the hair boom series and uses a safe low-power laser therapy (LLLT). The laser generated from the LD terminal is examined evenly throughout the scalp to activate follicle cell proliferation, increase blood flow, and supply sufficient nutrition and oxygen to the hair muscles with smooth blood flow to create healthy hair and strengthen the thickness of hair.

Based on the clinical results of equivalence, HairBoom Air has the advantage of being able to manage the entire scalp and easy to use because it is lighter helmet-type than previous devices.