

Medical Devices; General and Plastic Surgery Devices; Classification of the Focused Ultrasound System for Non-Thermal, Mechanical Tissue Ablation

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The Food and Drug Administration (FDA) is classifying the focused ultrasound system for non-thermal, mechanical tissue ablation into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the focused ultrasound system for non-thermal, mechanical tissue ablation. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

Agency: Health and Human Services Department, Food and Drug Administration.

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