

Medical Devices; Immunology and Microbiology Devices; Classification of the High Throughput DNA Sequencing for Hereditary Cancer Predisposition Assessment Test System

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The Food and Drug Administration (FDA) is classifying the high throughput DNA sequencing for hereditary cancer predisposition assessment test system 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 high throughput DNA sequencing for hereditary cancer predisposition assessment test system. 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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