

Medical Devices; Immunology and Microbiology Devices; Classification of the Hematopoietic Cell Enrichment Kit

Published October 9, 2026

District of Columbia statewide, DC - District of Columbia statewide County, DC

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The Food and Drug Administration (FDA) is classifying the hematopoietic cell enrichment kit 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 hematopoietic cell enrichment kit. 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.

Document type: Rule.

Document number: 2026-20725.

Official Federal Register document. Matter furnished by the National Archives Federal Register API. Notice Nearby is not the publisher of record for this item.

Source:

<https://www.federalregister.gov/documents/2026/10/09/2026-20725/medical-devices-immunology-and-microbiology-devices-classification-of-the-hematopoietic-cell>