

Medical Devices; Cardiovascular Devices; Classification of the Infant Pulse Rate and Oxygen Saturation Monitor for Over-the-Counter Use

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The Food and Drug Administration (FDA) is classifying the infant pulse rate and oxygen saturation monitor for over-the-counter use 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 infant pulse rate and oxygen saturation monitor for over-the-counter use. 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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