COSMOS
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42 C.F.R. § 405.201

Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as Category B (Nonexperimental/investigational) device.

(3) CMS identifies criteria for coverage of items and services furnished in IDE studies.

(b) *Definitions.* As used in this subpart—

Category A (Experimental) device refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.