

42 C.F.R. § 405.205

Coverage of a Category B (Nonexperimental/investigational) device.

(a) For any device that meets the requirements of the exception at § 411.15(o) of this chapter, the following procedures apply:

- (1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category B (Nonexperimental/investigational).

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