

21 U.S. Code § 360g

Judicial review

(a) Petition; record

Not later than thirty days after—

- (1) the promulgation of a regulation under section 360c of this title classifying a device in class I, an administrative order changing the classification of a device to class I, or an order under subsection (f)(2) of such section reclassifying a device or denying a petition for reclassification of a device,
- (2) the promulgation of a regulation under section 360d of this title establishing, amending, or revoking a performance standard for a device,
- (3) the issuance of an order under section 360d(b)(2) or 360e(b)(2)(B) of this title denying a request for reclassification of a device,
- (4) the promulgation of a regulation under paragraph (3) of section 360e(b) of this title requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 360e(g)(1) or 360e(g)(2)(C) of this title,
- (5) the promulgation of a regulation under section 360f of this title (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

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