

§5.401

for which a person may submit a declaration of conformity in order to meet a premarket submission requirement.

(b) These officials may not further redelegate this authority.

§5.401 Issuance of Federal Register documents pertaining to exemptions from premarket notification.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health; and the Directors and Deputy Directors, Center for Biologics Evaluation and Research, are authorized to make determinations and issue FEDERAL REGISTER notices and rules under section 510(m) of the act (21 U.S.C. 360(m)) concerning exemptions from premarket notification.

(b) These officials may not further redelegate this authority.

§5.402 Detention of adulterated or misbranded medical devices.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)) and in accordance with §800.55 of this chapter, of medical devices that may be adulterated or misbranded:

(1) For medical devices assigned to their respective organizations:

(i) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(iv) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(b) These officials may not further redelegate this authority.

21 CFR Ch. I (4–1–03 Edition)

§5.403 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(a)(3)(B)) the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the act (21 U.S.C. 360c, 360d, and 360e):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Director, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVR), and Office of Therapeutics Research and Review (OTRR), CBER.

(b) These officials may not further redelegate this authority.

§5.404 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections 513(f) and 520(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f) and 360 j(1)) and denials of petitions for reclassification of medical devices that are submitted under section 513(e) of the act (21 U.S.C. 360c(e)) (except for petitions submitted in response to FEDERAL REGISTER notices initiating standard-setting under section 514(b) of the act (21 U.S.C. 360d(b)) or premarket approval under section 515(b) of the act (21 U.S.C. 360e(b))):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

(b) These officials may not further redelegate this authority.

§ 5.405 Determination of classification of devices.

(a) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device in commercial distribution prior to May 28, 1976, under section 513(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(d)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors of the Office of Blood Research and Review (OBRR), the Office of Vaccines Research and Review (OVR), and the Office of Therapeutics Research and Review (OTRR), CBER.

(b) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, under section 513(f)(1)(A) of the act (21 U.S.C. 360c(f)(1)(A)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director, Deputy Directors, Division and Deputy Division Directors, Associate Division Directors, Branch Chiefs, and Chief, Premarket Notification Section, ODE, CDRH.

(2) The Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVR, and OTRR, CBER.

(c) The following officials are authorized to make determinations and issue orders classifying devices under section 513(f)(2)(b):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Directors, ODE, CDRH.

(3) The Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVR, and OTRR, CBER.

(d) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVR, and OTRR, CBER, are authorized to issue FEDERAL REGISTER notices under section 513(f)(2)(C) of the act (21 U.S.C. 360c(f)(2)(C)) announcing classification of devices under section 513(f)(2)(B) of the act (21 U.S.C. 360c(f)(2)(B)).

(e) These officials may not further redelegate those authorities.

§ 5.406 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f) and 360j(1)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.