The *Riegel* Court reiterated that the generic requirements that the FDA imposes across the board on almost all medical devices, and the review it conducts to determine whether a device qualifies for grandfathering, do not necessarily result in preemption. Accordingly, when the plaintiff’s complaint is based on poor manufacturing practices, such as contamination or poor quality control, the court should determine whether the FDA has imposed any device-specific requirements regarding these practices. If not, then there should be no preemption at all. In addition, most courts hold that a claim that is based on a violation of the FDA manufacturing standards is not preempted.

### Footnotes


237 See, e.g., Mink v. Smith & Nephew, Inc., 860 F.3d 1319 (11th Cir. 2017) (negligence claim based on longstanding state law duty to use care in manufacturing is not preempted).

238 [222] Godella v. Zoll Services, L.L.C., 881 F.3d 1309 (11th Cir. 2018); Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010) (both common law and statutory claims are preserved, and claim can be based on violation of either device-specific requirements or general manufacturing requirements); Howard v. Sulzer Orthopedics, Inc., 382 Fed. Appx. 436 (6th Cir. 2010) (claim based on manufacturer’s violation of the FDA’s general manufacturing standards is not preempted); Silver v. Medtronic, Inc., 236 F. Supp. 3d 889 (M.D. Pa. 2017); Sadler v. Advanced Bionics, 929 F. Supp. 2d 670 (W.D. Ky. 2013) (allowing parallel claim to proceed based on manufacturer’s violation of the FDA’s specific manufacturing requirements for this device and on specific requirement for testing in the FDA’s generic manufacturing requirements); Tillman v. Smith & Nephew, Inc., 2013 WL 3776973 (N.D. Ill. July 18, 2013) (claim based on violation of the FDA’s generic manufacturing requirements is not preempted); Purchase v. Advanced Bionics, L.L.C., 896 F. Supp. 2d 694 (W.D. Tenn. 2011) (parallel claim can be based on the FDA’s general manufacturing standards as long as the particular standard is not so vague as to be incapable of enforcement); James v. Diva Int’l, Inc., 803 F. Supp. 2d 945 (S.D. Ind. 2011); Warren v. Howmedica Osteonics Corp., 2010 WL 5093097 (E.D. Mo. Dec. 8, 2010) (claims based on violation of FDA reporting, quality assurance, and other procedures are not preempted). Cf. Eggerling v. Advanced Bionics, L.L.C., 958 F. Supp. 2d 1029 (N.D. Iowa 2013) (applying the general provisions of the FDA’s manufacturing standards in the device-specific way that would be necessary for state tort liability would amount to imposing additional requirements and is preempted, but the standards’ testing requirements are sufficiently specific and a claim based on them is not preempted). But see Gross v. Stryker Corp., 858 F. Supp. 2d 466, 492–497 (W.D. Pa. 2012) (refusing to treat manufacturer’s failure to comply with the FDA’s broad, general manufacturing standards as a parallel claim); Cenac v. Hubbell, 2010 WL 4174573 (E.D. La. Oct. 21, 2010) (dismissing state claims based on poor manufacturing practices without identifying a device-specific requirement on the topic; also holding that the FDA’s general manufacturing requirements are too vague to be the basis for a parallel claim).