

UCSF HUMAN RESEARCH PROTECTION PROGRAM
EXEMPTIONS FROM IDE REQUIREMENTS

According to Food and Drug Administration (FDA) regulations [21 CFR 812.2](#), investigations of the following categories of devices are exempt from requirements to submit an Investigational Device Exemption (IDE) application to the FDA.

- (1) A device, other than a [transitional device](#), in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
- (2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
- (3) A diagnostic device, if the sponsor complies with applicable requirements in [21 CFR 809.10\(c\)](#) and if the testing:
 - (a) Is noninvasive,
 - (b) Does not require an invasive sampling procedure that presents significant risk,
 - (c) Does not by design or intention introduce energy into a subject, and
 - (d) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- (4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
- (5) A device intended solely for veterinary use.
- (6) A device shipped solely for research on or with laboratory animals and labeled in accordance with [21 CFR 812.5\(c\)](#).
- (7) A custom device as defined in [21 CFR 812.3\(b\)](#), unless the device is being used to determine safety or effectiveness for commercial distribution.

Note that investigations of nonsignificant risk devices are considered by the FDA to have approved IDE applications. For additional discussion of research on medical devices, see [HRPP Guidance on Investigational Devices](#).