Under a new amendment to the IDE regulation (21 CFR 812.35(a)(3)), sponsors may make certain modifications to their device design/manufacturing process and/or their clinical protocol without prior FDA approval of a supplement if the changes are reported to the Agency within 5 days of implementation. (Section 520(g)(6) of the act) For developmental changes in the device (including manufacturing modifications), the change must not constitute a significant change in design or in basic principles of operation of the device. To help sponsors decide if a proposed change meets these statutory criteria, the regulation recommends that sponsors use design controls, preclinical/animal testing, peer reviewed published literature, or other information, such as preliminary results of their clinical trial or marketing experience gained outside the U.S. Protocol changes that do not affect the rights, safety or welfare of the subjects, scientific soundness of the investigational plan, validity of the data, or the risk to benefit relationship may also be made without prior FDA approval. As with device modifications, the sponsors should use peer reviewed published literature, preliminary results of their clinical trial or marketing experience gained outside the U.S., or the recommendations of their clinical investigators to support the protocol changes. If there is any question whether a proposed device/manufacturing or protocol change would meet the statutory criteria for implementation without prior FDA approval, sponsors are encouraged to consult the guidance document entitled, "Changes or Modifications During the Conduct of a Clinical Investigation" (www.fda.gov/cdrh/ode/guidance/1337.pdf) or to discuss the change with the IDE Staff or the appropriate review division.

By allowing IDE sponsors to proceed with certain types of device design/manufacturing and protocol changes without prior FDA approval of an IDE supplement, the regulatory burden on IDE sponsors should be reduced. Furthermore, the alternative approaches provided to IDE sponsors in the regulation exemplify the sound application of the least burdensome principles.