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The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations governing classification and reclassification of medical devices to conform to the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Food and...Summary of MDR Regulation. On July 31, 1996, the new Medical Device Reporting (MDR) regulation became effective for user facilities and device manufacturers.The Food and Drug Administration (FDA or we) is amending its regulations on acceptance of data from clinical investigations for medical devices. We are requiring that data submitted from clinical investigations conducted outside the United States intended to support an investigational device...ISO 9001 and Regulatory Compliance In the Medical Device Industry. Lack of attention to quality systems can result in hefty fines, indirect costs