Marjorie Shulman has been with the Center for Devices and Radiological Health (CDRH) within the Food and Drug Administration since 1984. She is currently the Acting Director for the Premarket Notification Staff (510(k) Staff) in the Office of Device Evaluation (ODE). Before serving on the 510(k) Staff she was on the Premarket Approval Staff. Ms. Shulman is also the Reclassification/Classification Coordinator for CDRH. Some of her accomplishments include drafting guidance documents and regulations regarding the 510(k) program, training staff, and assisting in the implementation of the Medical Device User Fee Modernization Act (MDUFMA) and FDA Modernization Act (FDAMA). Ms. Shulman has been on numerous policy setting groups within the FDA. Most recently she has been very active with the 510(k) Working Group whose mission it is to evaluate the 510(k) program and explore actions CDRH could take to enhance 510(k) decision making. Ms. Shulman received her undergraduate degree from the University of Maryland, University College, and received her MBA from Hood College in May 1997.