This guidance document is outdated and has been removed from CDRH's web site. An archived copy may be obtained from CDRH's Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), please contact dsmica@cdrh.fda.gov. Devices previously covered by this document that are eligible for 510(k) third party review will retain "non-pilot" status pending CDRH's issuance of updated guidance. Additional information about the third party review program is available at http://www.fda.gov/cdrh/thirdparty/.