

We are withdrawing this manual because the information is outdated. Please see the CDRH Device Advice page <http://www.fda.gov/cdrh/devadvice/pma> for updated information. For questions regarding this document, please contact Gene Allen at 301 443-6597 x114 or email [dsmica@cdrh.fda.gov](mailto:dsmica@cdrh.fda.gov)