

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

50-780

STATISTICAL REVIEW(S)

10. Statistical Section

There are no descriptions of statistical evaluations included in this application. These descriptions are not required since no clinical studies were performed by B. Braun Medical Inc. to support this application. B. Braun Medical Inc. has relied on the clinical studies performed on the reference listed drug, Glaxo Wellcome's Zinacef® sterile cefuroxime sodium and cefuroxime sodium injection (NDA 50-558).