March 1993

FINAL REPORT OF THE COMMITTEE FOR CLINICAL REVIEW

BASED ON A REVIEW OF SELECTED MEDICAL DEVICE APPLICATIONS

EXECUTIVE SUMMARY

At the request of the Commissioner of Food and Drugs, a committee primarily composed of experienced clinical and statistical reviewers from the Center for Drug Evaluation and Research was formed to provide clinical support to the Center for Devices and Radiological Health (See Appendix I). The Committee on Clinical Review was asked to perform reviews of selected pending and approved applications for medical devices. The Committee was also asked to provide CDRH with recommendations on improving the clinical review process. This final report contains the Committee's findings on the deficiencies in the clinical data submitted to CDRH in support of PMA's and 510(k)'s. These findings have been sent to and reviewed by CDRH and each of the Chairs of the advisory committees that provide recommendations to CDRH on medical device applications. Several of the Advisory Committee Chairs provided written comments on the Committee's findings. These comments are summarized in the final report. In addition the final report contains recommendations to CDRH on improving the quality of the data submitted in device applications.

Preliminary Findings

The findings contained in this report are based on a small sample