Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices 5/1/95 (G95-1)

NOTE: This memo was distributed with Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and relates to implementation of #G95-1.

May 1, 1995

Director, Office of Device Evaluation (ODE)

Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices

Division Directors, ODE

The new blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing," includes an FDA-modified matrix that designates the type of testing needed for various medical devices (copy attached). It also includes a flow chart entitled "Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s." The guidance will be effective for all submissions that will be received on or after July 1, 1995. The former guidance, #G87-1 entitled "Tripartite Biocompatibility Guidance," may continue to be applied until a final decision is reached on each submission received