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## X. Summary of Safety and Effectiveness

**Submitter:** Marian Harding Cochran, J.D., Regulatory Affairs Manager  
Dade International Inc., Miami FL. 33172

**Date:** January 5, 1996

### Device Names:

- Moni-Trol® Level 1 Chemistry Control and Carbonate Diluent 1, Moni-Trol® Level 2 Chemistry Control and Carbonate Diluent 2
- Moni-Trol® Level 1 Chemistry Control, Moni-Trol® Level 2 Chemistry Control and Moni-Trol® Level 3 Chemistry Control
- Moni-Trol® Level 1X Chemistry Control and Carbonate Diluent 1, Moni-Trol® Level 2X Chemistry Control and Carbonate Diluent 2
- Moni-Trol® Level 1X Chemistry Control, Moni-Trol® Level 2X Chemistry Control and Moni-Trol® Level 3X Chemistry Control
- Moni-Trol® Calibrator A and Carbonate Diluent 1, Moni-Trol® Calibrator B and Carbonate Diluent 2
- Moni-Trol® Calibrator A, Moni-Trol® Calibrator B and Moni-Trol® Calibrator C

### Predicate Devices:

- Dade® Moni-Trol® Chemistry Control / Calibrator (K871977); Moni-Trol® and Other Brand names Chemistry Control / Calibrator, (K891929/A); Dade® Urine Chemistry Control; Dade® Immunoassay Control; Dade® Anemia/Hemochromatosis Control; Dade® CK/LD Control
- BIO-RAD Lyophochek® Chemistry Control, Liquichek™ Immunology Control, Liquichek™ Rheumatoid Factor Control
- CIBA-CORNING QCS® Control Serum
- Boehringer Mannheim Precical®
- Beckman CAL 1

### Intended Uses:

- Dade® Moni-Trol® Control is intended for use as an unassayed quality control material in quantitative clinical chemistry control programs.
- Dade® Moni-Trol® Control is intended to assist in the control of accuracy and precision of clinical chemistry quality control programs.
- Dade® Moni-Trol® Calibrator is intended for use as a calibrator in the quantitative determination of clinical assays.

**Comparison of the candidate device to the predicate devices:** Comparison of intended uses, base material and constituents supports the determination of substantial equivalence.

**Performance data:** Non-clinical tests for typical analyte values, shelf-life and reconstituted stability submitted in the premarket notification support the conclusion that the candidate device is as safe and effective, and performs as well as or better than the legally marketed devices identified in this summary.