

K970431

MAY -5 1997

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For Behring Coagulation System**

1. Manufacturer and Contact Information:

Manufacturer: Behring Diagnostics GmbH
P.O. Box 1149
35001 Marburg, Germany

Contact Information: Paul Rogers
Behring Diagnostics Inc.
3403 Yerba Buena Road
P.O. Box 49013
San Jose, CA 95161-9013
Tel: 408-239-2000

2. Device Classification Name:

The Behring Coagulation System is a Class II device and is classified as a multipurpose system for *in vitro* coagulation studies (21 CFR §864.5425).

3. Intended Use:

The Behring Coagulation System is an instrument intended to perform quantitative assays of specific parameters in plasma.

4. Substantial Equivalence:

Behring Diagnostics Inc. considers the BCS to be substantially equivalent to the Behring Coagulation Timer (K955278) and the Behring Fibrintimer A (K926551) in terms of intended use, instrument features, and overall performance characteristics.

5. Device Description and Performance Characteristics:

The Behring Coagulation System (BCS) is a fully automated coagulation instrument. The BCS is used in conjunction with Behring Diagnostics test kits to perform various coagulometric and chromogenic coagulation tests.

Comparative Analysis: Sample correlation data were collected on the BCS and either the BCT of BFA instruments using various coagulometric and chromogenic assays. Regression analysis on each assay used showed a range of correlation coefficients from 0.97 to 0.996.

Precision: Precision studies were performed following the NCCLS EP5 guideline using samples which were in the normal and abnormal ranges of various coagulation assays. The within-run precision ranged from 0.5 to 6.3%. The total precision ranged from 0.90 to 8.1%.