

Attachment 1**510(k) Summary of Safety and Effectiveness for
Behring Coagulation Timer****1. Manufactures Name, Address, Telephone, and contact person, date of preparation:**

Manufacturer Behringwerke AG
Postfach 1140
35001 Marburg
Germany

Distributor Behring Diagnostics Inc.
151 University Avenue
Westwood, MA 02090
617-320-3000
Attn: Kathleen Dray-Lyons

Preparation date: November 16, 1995

2. Device Name/ Classification:

Behring Coagulation Timer: multipurpose system for in vitro coagulation studies
Classification Number: class II (864.5425)

3. Identification of the legally marketed device:

Behring Fibrintimer A

4. Proposed Device Description:

Behring Coagulation Timer (BCT) is a fully automatic photo-optical coagulation instrument. The BCT is used in conjunction with the Behringwerke AG test kits for measurement of coagulation, fibrinolysis factors and inhibitors as well as to measure the function of the homeostatic system as a whole.

5. Proposed Device Intended Use:

Behring Coagulation Timer is a photometric coagulation analyzer intended for clinical use to perform all coagulometric, chromogenic and immunologic coagulation tests.

6. Medical device to which equivalence is claimed and comparison information:

The Behring Coagulation Timer (BCT) is substantially equivalent in intended use and results obtained to the Behring Fibrintimer A (BFA) which was the subject of 510(k) K926551 . The BCT like the BFA performs fully automatic, rapid quantitative measurement of coagulation time by optical detection. Both analyzers use photometric technology and offer continuous access operation. Both the BCT and the BFA process samples in the Random Access mode.

The BCT differs from the BFA in that the BCT can provide an Autostart with barcoded samples along with an integrated barcode scanner.

The BCT also differs from the BFA in that the BCT performs three basic types of assays clotting (fibrin clot), chromogenic (color development), and Immunologic (antibodies + latex) whereas the BFA can perform only clotting assays.

7. Proposed Device Performance Characteristics:

Correlation:

Performance characteristics of the Behring Coagulation System and the Behring Fibrintimer A were compared by evaluating several representative assays. The two clotting assays evaluated were Thromborel S and Pathromtin. For Thromborel S, 83 samples were evaluated on the BCT vs. the BFA. A correlation coefficient of 0.997 with a y-intercept of 0.72 and a slope of 0.97.

For Pathromtin, 83 samples were evaluated on the BCT vs the BFA. A correlation coefficient of 0.99 was obtained, with a y-intercept of -0.87 and a slope of 1.0.

The two colorometric assays which were evaluated were Berichrom Plasminogen and Berichrom Protein C. For the Berichrom Plasminogen, 58 samples were evaluated on the BCT vs the Behring Chromotime System (K901829). A correlation coefficient of 0.96 was obtained, with a y-intercept of 9.9 and a slope of 0.97.

For Berichrom Protein C, 74 samples were evaluated on the BCT vs the Behring Chromotime System. A correlation coefficient of 0.99 was obtained, with a y-intercept of -0.69 and a slope of 1.0.

These studies support the substantial equivalence of the BCT and the BFA.

Precision:

Precision of the BCT was evaluated using the above mentioned representative assays. Each level of control was run in replicates of 8 for five days, to total n=40. Intra-assay precision was calculated from either an n=4 or n=8 precision values over the 5 days. Precision data is summarized in the table below.

Thromborel S: **BCT**
3 levels ranging from 11 to 59 secs

Intra-Assay %CV 0.50 to 0.81

Inter-Assay %CV 2.04 to 6.36

Pathromtin: **BCT**
3 levels ranging from 37 to 91 sec

Intra-Assay %CV 1.55 to 2.95

Inter-Assay %CV 1.75 to 2.51

Berichrom Plasminogen: **BCT**
3 levels ranging from 38.52 to 111.74 % norm

Intra-Assay %CV 2.85 to 3.61

Inter-Assay %CV 2.19 to 3.95

Berichrom Protein C: **BCT**
3 levels ranging from 77 to 104 % norm

Intra-Assay %CV 3.33 to 3.96

Inter-Assay %CV 1.90 to 2.54