

Section 1—General Submission Summary Information

Classification Name: Automated Blood Grouping and Antibody Test System

Common Name: Automated Blood Grouping and Antibody Screening Analyzer

Trade/Proprietary Name: TANGO Automated Blood Bank Analyzer System

Establishment Registration Number: 9610824 Analyzer Manufacturer (Biotest GmbH)
2429304 US Distributor (Olympus America Inc.--
Diagnostic Systems Group)

See Attachment 1.1 for more explanations of the
Manufacturing and Distribution Relationship

System Elements Classifications and
Product Codes:

TANGO Automated Blood Bank Analyzer	21 CFR 864.9175 Class II 81 KSZ
Negative Control *Not a stand alone product, but integrated into the Erytype Strips	21 CFR 864.9650 Class II 81 KSF
Solidscreen II Control	21 CFR 864.9650 Class II 81 KSF
Modified LISS (Low Ionic Strength Solution) Reagent	21 CFR 864.9600 Class II (exempt) 81 KSG
Bromelin Solution	21 CFR 864.9400 Class II 81 KSK
Erytype-S ABD+Rev. A1,B test strip	21 CFR 864.9175 Class II 81 KSZ
Erytype-S ABO Donor Strip	21 CFR 864.9175 Class II 81 KSZ
Erytype-S Rh Donor Strip	21 CFR 864.9175 Class II 81 KSZ
Solidscreen II Antibody Screening Strip	21 CFR 864.9175 Class II 81 KSZ

**OTHER ELEMENTS OF THE
TANGO SYSTEM THAT ARE
LICENSED BIOLOGICAL
MATERIALS (LISTED HERE TO
DEMONSTRATE COMPLETE
TANGO SYSTEM)**

**These reagents, and thus the entire
TANGO System, will not be sold
into interstate commerce until the
appropriate BLA application or
supplement has been approved by
FDA.**

For ABO/Rh Determinations

1. Biotest Diagnostics Anti-A Blood Grouping Reagent
2. Biotest Diagnostics Anti-B Blood Grouping Reagent
3. Biotest Diagnostics Anti-A,B Blood Grouping Reagent
4. Biotest Diagnostics Anti-D (two separate clones) Blood Grouping Reagent
5. Medion Diagnostics Reverse-Cyte® Reagent Red Blood Cells

For Antibody Screening Determinations

1. Biotest Diagnostics Anti-Human Globulin Anti-IgG Solidscreen II
2. Medion Diagnostics Search Cyte® Reagent Red Blood Cells (Pooled, Duo, and Trio screen cells)

Performance Standards:

None established under section 514 of the Food, Drug and Cosmetic Act

Labeling Material:

Draft Labeling material indicating the changes that will be necessary as a result of this modification are included in this submission.

Substantial Equivalence:

This modification is substantially equivalent to the predicate devices and biological products identified in section 2 of this submission.

Safety and Efficacy:

In accordance with the Safe Medical Devices Act of 1990, safety and effectiveness information will be made available to any person upon request.