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VI. Summary of Safety and Effectiveness Information

TAS aPTT Controls

Trade name: Thrombolytic Assessment System activated Partial Thromboplastin Test Controls (TAS aPTT Controls)

Common Name: in vitro coagulation controls

Classification Name: systems for in vitro coagulation studies, automated or semiautomated instruments and associated reagents and controls used to perform a series of coagulation studies and coagulation factor assays (Class II. 21 C.F.R. 864.5425)

Predicate Device: In clinical comparison studies the TAS aPTT Controls provided results that compared well with other legally marketed controls for the aPTT test (Ci-trol; Dade; Baxter Diagnostics, Inc.) when used to test the operation of the TAS Analyzer and test cards. The TAS aPTT Controls are substantially equivalent to the Dade controls, in performance and in intended use, but are specifically to be used with the TAS Analyzer and aPTT test cards. The Dade controls are used with instruments from many different manufacturers, including the TAS Analyzer, to determine the aPTT, a test which is used to screen for factor deficiencies and inhibitors in the intrinsic and common pathways, and to monitor anticoagulant therapy.

Description of the Device: The controls for TAS aPTT cards consists of two separate vials. One was designed to mimic a sample from a normal individual, and the second to mimic a sample from a patient with a clotting factor deficiency of the intrinsic or common coagulation pathway. These controls are made with human plasma screened for antibodies to and antigens of human immunodeficiency and hepatitis viruses. To make the controls as easy to use as possible for point-of-care testing, we chose the patented packaging system of EDItek. This consists of a closed, crushable glass ampule containing lyophilized plasma which is inside a plastic sleeve. The sleeve contains water for diluent and has a capped dropper top with a filter tip. The entire assembly is shrink wrapped with a label and plastic seal. To use, the ampule is crushed inside the plastic sleeve, which allows the diluent to mix with the lyophilized plasma. The mixture is reconstituted by shaking or vortexing the capped vial. The plastic seal and cap are removed, two drops of plasma are discarded into a biohazard waste container, and a drop of the plasma suspension is added to a TAS aPTT test card in an analyzer. The rest of the test procedure and the manner of signal production is identical to that for a patient sample.

Intended Use: The new TAS aPTT Controls are intended to be used with the TAS Analyzer and aPTT cards, cleared by the FDA, to provide a method for quality control of the system. The controls produce clotting times which must be within accepted, standard ranges, to indicate that the analyzer and test cards are functioning properly and thereby help assure the accuracy of aPTT test results. The controls are substantially equivalent in intended use to other controls used in coagulation assays.

Summary of Safety and Effectiveness Information**TAS aPTT Controls****Comparison of the TAS aPTT Controls to the Marketed Controls:**

<u>Characteristic</u>	<u>TAS aPTT Controls</u>	<u>Dade Controls</u>
Intended use	assure performance of system by functional testing	same
For use with	TAS aPTT test cards	coagulation systems that measure the PT and aPTT
	citrate coagulation test system	same
Format	glass ampule in plastic sleeve	capped glass bottle
Reagent	lyophilized plasma	same
Diluent	water	same
Source	human	same
Reaction	formation of a fibrin clot	same
Results	clotting time (seconds)	same
Interpretation of results	system OK if clotting times are within set limits	same

There were no significant differences in the performance of the TAS aPTT Controls and the control from another manufacturer used as predicate device. The normal control produces a clotting time like that of a normal individual (but have different times for different reagent/instrument combinations). Like other control manufacturers, we chose to make an abnormal control that responds like a patient that has a severe factor deficiency of the intrinsic coagulation pathway. The method of packaging TAS controls is different, to make them more "user-friendly" for point-of-care testing. With this system, an operator does not have to search for a pipetting device and reagent-grade water for reconstitution, and does not have to wait for the reagent to reconstitute.