CARDIOVASCULAR DIAGNOSTICS INC.

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510(k) Summary

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VI. Summary of Safety and Effectiveness Information HMT Controls

Trade name: Thrombolytic Assessment System Heparin Management Test Controls (TAS HMT 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 HMT controls provided results that compared well with legally marketed controls, the ACT-trol controls for the Activated Clotting Time Test (Analytical Control Systems, ACS) when used to test the operation of the instrument and test cards. The TAS HMT controls are substantially equivalent to the ACS controls. These latter controls are used in conjunction with disposable tubes for the Hemochron or Hemotec devices, which are used to determine a patient's response to high doses of heparin, which also is the intended use of the TAS Analyzer and HMT cards (see K943283).

Description of the Device: The controls for TAS HMT 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 on a high dose of heparin. 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 waste container, and a drop of the plasma suspension is added to a TAS HMT 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 HMT controls are intended to be used with the TAS Analyzer and HMT cards, previously cleared to market 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 the HMT test results. The controls are substantially equivalent in intended use to other controls used in coagulation assays.

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Comparison of the TAS HMT Controls to the Marketed Controls:

Characteristic	HMT Controls	ACT Controls
Intended use	assure performance of system by functional testing	same
For use with	HMT cards that measure response to heparin	tests that measure response to heparin
Format	glass ampule in plastic sleeve	capped glass bottle
Reagent	lyophilized plasma	same
Diluent	water	same
Source	human	same or animal
Reaction	formation of a fibrin clot	same
Results	clotting time	same
Interpretation of results	system OK if clotting times are within set limits	same

There were no significant differences in the performance of the HMT controls and the controls from other manufacturers used as predicate device. The normal controls produce a clotting time like that of a normal individual (but have different times for different reagent/instrument combinations). As other control manufacturers, we chose to make an abnormal control that responded as a patient would that is near the mid-range in heparin response. 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 30 minutes for the reagent to reconstitute.

Nonclinical Performance Data:

HMT controls are stable for at least 15 weeks of storage at room temperature, indicating a probable refrigerator stability of at least one year. Controls produced acceptable results for about 30 minutes after reconstitution, but we recommend that they be run as soon as possible after reconstitution, preferably within five minutes.

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Within day, day to day, operator to operator, lot to lot, vial to vial, drop to drop variation studies all produced mean ranges of 133 - 153 and 235 - 260 for the normal and heparin controls, respectively, with CV ranging from 5 to 9%.

Freezing or warming of the intact vials to incubator temperatures for short periods of time has little, if any, effect on the performance of these controls - there was no significant difference in mean or CV for any of the samples tested compared to vials stored in the refrigerator. Temperature of the vials or sample temperature has little, if any effect on the HMT cards results produced with these controls. The angle at which drops from the control vials are dispensed has no significant effect on the mean clotting times or the CV of the results.

Clinical Performance Data:

Studies were performed at two clinical study sites and at CDI to establish the performance of the TAS HMT controls in the field. At each of the clinical study sites, the TAS HMT normal and heparin controls were tested in duplicate each day for 20 days with the TAS Analyzer and HMT test cards to determine variation.

	Normal		Heparin	
	Mean	CV	Mean	CV
Site A	135	9.8	245	4.2
Site B	133	8.3	245	3.2
CDI	150	7.9	259	6.4

Conclusions: TAS HMT controls are substantially equivalent to the predicate device because they have the same intended use and the similar technological characteristics. This application includes sufficient information to demonstrate that the TAS HMT controls, to be used with the TAS Analyzer (K933092) and TAS HMT cards (K943283), are safe and effective as a legally marketed device, and that they do not raise different questions of safety and efficacy.

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