

K961750

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Exhibit 21. 510(k) Summary

FEDERAL FOOD, DRUG AND COSMETIC ACT  
510(k) SUMMARY  
**DOCUMENT<sup>®</sup> CARDIAC Assayed Control, Levels I, II, III**

1. Submitted by: CASCO Standards  
P.O. Box 970  
Yarmouth, ME 04096

Attention: Christine V. Beach  
Manager, Regulatory Affairs

(207) 878-7550  
(207) 878-7578 FAX

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2. Product Name:

Proprietary Name: **DOCUMENT<sup>®</sup> CARDIAC Assayed Control**

Classification Name: Control, multiple analyte, assayed.

3. Predicate Device:

Product: Dade CK-MB/Myoglobin Immunoassay Control Level 1,2 and 3  
Catalog: Level 1 (B5200-1), Level 2 (B5200-2), Level 3 (B5200-3)  
Manufacturer: Baxter Diagnostics, Inc., Deerfield, IL 60015-4633  
Analytes: CK-MB, Myoglobin

Product: Abbott IMx STAT CK-MB Controls, L, M, H  
Catalog: 7A28-10  
Manufacturer: Abbott Laboratories, Abbott Park, IL 60064  
Analytes: CK-MB

Product: Bio-Rad Unassayed Chemistry Control (Human) Levels 1 and 2  
Catalog: 16030  
Manufacturer: Bio-Rad, ECS Division, Anaheim, CA 28506  
Analytes: CK, LD

Product: Beckman I.D-Zone Liquid CK Isoenzyme Control  
Catalog: 667990  
Manufacturer: Beckman Instruments, Brea, CA  
Analytes: CK

Product: Beckman I.D-Zone Normal LD Isoenzyme Liquid Control  
Catalog: 439090  
Manufacturer: Beckman Instruments, Brea, CA  
Analytes: LD

4. Product Description: **DOCUMENT<sup>®</sup> CARDIAC Assayed Controls** consist of three levels of a human serum matrix containing creatine kinase isoenzymes, lactate dehydrogenase isoenzymes 1 and 2, and myoglobin. The formulation design provides a liquid matrix intended for use on automated and semi-automated immunochemistry systems and clinical chemistry systems for the determination of total creatine kinase activity (CK), creatine kinase MB mass (CKMB), creatine kinase immunoinhibition (CKII), creatine kinase electrophoresis (CKELEC), total lactate dehydrogenase activity (LD), lactate dehydrogenase electrophoresis for isoenzyme 1 and 2 (LD1; LD2), and myoglobin (MYO).

5. Intended Use: This product is intended for *in vitro* diagnostic use as a control product to assess the analytical performance of immunochemistry systems and clinical chemistry systems using methods for the quantitative measurement of the listed analytes. It is intended to provide the necessary control material required by inspection agencies for the evaluation of system performance. In addition, it will provide assistance when troubleshooting chemistry systems, reagent problems and calibration anomalies.

6. Comparison to the Predicate Device:

Characteristic	<b>DOCUMENTI<sup>®</sup></b> CARDIAC Assayed Control	Dade CK-MB/Myoglobin Immunoassay Control	Abbott CK-MB Stat Control	Bio-Rad Liquichek Unassayed Chemistry Control
Intended Use	Assayed control for monitoring accuracy and precision of total CK and LD activity, CKMB immunoassay, CK Immuno-inhibition, CK isoenzyme electrophoresis, LD1 and LD2 isoenzyme electrophoresis, myoglobin	Assayed control for monitoring of the accuracy and precision of CK-MB and myoglobin analysis	None indicated	Unassayed control for the monitoring of the accuracy and precision of automated and manual testing procedures
Number of Levels	Three (3): Level I, Level II, Level III	Three (3): Level 1, Level 2, Level 3	Three (3): Low, Mid, High	Two (2): Level 1, Level 2
Type	Assayed	Assayed	Assayed	Unassayed
Analytes	3	2	1	Many
Volume	2 mL	3 mL	8 mL	5 mL
Matrix	Human serum, Liquid	Human source, Lyophilized	Bovine serum, Lyophilized	Human serum, Liquid
Dilution	None required	None required	None required	None required
Unopened Stability	Until Expiration Date	Until Expiration Date	Until Expiration Date	Until Expiration Date
Open Stability	45 Days	CKMB: 20 Days MYO: 14 Days	None indicated	15 Days
Container	Plastic, Dropper Tip	Glass	Plastic, Dropper Tip	Glass

6. Comparison to the Predicate Device (Continued):

Characteristic	<b>DOCUMENTI</b> <sup>®</sup> CARDIAC Assayed Control	Beckman I.D-Zone Liquid CK Isoenzyme Control	Beckman I.D-Zone Liquid LD Isoenzyme Control
Intended Use	Assayed control for monitoring accuracy and precision of total CK and LD activity, CKMB immunoassay, CK immunoinhibition, CK isoenzyme electrophoresis, LD1 and LD2 isoenzyme electrophoresis, myoglobin	Assayed control for monitoring the overall reliability of CK isoenzyme procedures	Assayed control for monitoring the overall reliability of LD isoenzyme electrophoretic procedures
Number of Levels	Three (3): Level I, Level II Level III	One (1)	One (1)
Type	Assayed	Assayed	Assayed
Analytes	3	1	1
Volume	2 mL	2 mL	2 mL
Matrix	Human serum, Liquid	Human serum albumin, Liquid	Human serum, Liquid
Dilution	None required	None required	None required
Unopened Stability	Until Expiration Date	Until Expiration Date	Until Expiration Date
Open Stability	45 Days	20 Days	20 Days
Container	Plastic, Dropper Tip	Plastic Dropper Tip	Plastic, Dropper Tip

7. Test Results:

The equivalence for this product was carried out by comparing the inter-assay precision of the listed analytes of the **DOCUMENTI**<sup>®</sup>CARDIAC Assayed Control to that of Dade CK-MB/Myoglobin Immunoassay Controls, Abbott CK-MB Stat Controls, Bio-Rad Unassayed Chemistry Control, Beckman I.D-Zone Liquid CK Isoenzyme Control and Beckman I.D-Zone Normal LD Isoenzyme Liquid Control. The results show that the **DOCUMENTI**<sup>®</sup>CARDIAC Assayed Control behaves in a similar manner compared to the predicate devices and is suitable for use as a control for the listed analytes.