Exhibit 21. 510(k) Summary 962630 JUL 22 1996

FEDERAL FOOD, DRUG AND COSMETIC ACT
510(k) SUMMARY

DOCUMENT® Ammonia, Ethanol, Lactate 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

2. Product Name:

Proprietary Name: **DOCUMENT® Ammonia, Ethanol, Lactate Assayed Control**

Classification Name: Control, multiple analyte, assayed.

3. Predicate Device:

Product:	CASCO **DOCUMENT®** Ammonia/Ethanol (Protein-Based) Controls
Catalog:	LOW (P-110); MID (P-111), HIGH (P-112)
Manufacturer:	CASCO Standards, Portland, ME
Analytes:	Ammonia, Ethanol
Product:	Bio-Rad Liquichek Unassayed Chemistry Control (Human), Levels 1 and 2
Catalog:	16030
Manufacturer:	Bio-Rad, ECS Division, Anaheim, CA 28506
Analytes:	Lactate

4. Product Description: **DOCUMENT® Ammonia, Ethanol, Lactate Assayed Controls** consist of three levels of an aqueous matrix containing ammonia, ethanol, and lactate. The formulation design provides a liquid matrix intended for use on automated, semi-automated, and manual clinical chemistry systems for the determination of ammonia (AMM), ethanol (ALC), and lactate (LAC).

5. Intended Use: This product is intended for *in vitro* diagnostic use as a control product to assess the analytical performance of clinical chemistry systems using methods for the quantitative measurement of ammonia, ethanol, and lactate. 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	**DOCUMENT**® Ammonia, Ethanol, Lactate Assayed Control	**DOCUMENT**® Ammonia/Ethanol (Protein-Based) Liquid Control	Bio-Rad Liquichek Unassayed Chemistry Control
Part Number	P-114 / P-115 / P-116	P-110 / P-111 / P-112	691 / 692
Intended Use	Intended for *in vitro* diagnostic use as an assayed control on automated, semi-automated and manual clinical chemistry systems quantifying Ammonia, Ethanol, and Lactate.	Intended for *in vitro* diagnostic use as an indicator of analytical performance of systems quantifying Ammonia or Ethanol. This material is intended to serve as an assayed control material to aid in the assessment of day-to-day performance of such automated, semi-automated, and manual chemistry systems.	Intended for use as an unassayed quality control serum to monitor the accuracy and precision of an individual laboratory's automated and manual testing procedures.
Number of Levels	3	3	2
Type	Assayed	Assayed	Unassayed
Analytes	3	2	Many
Volume	4 mL	3 mL	5 mL
Matrix	Aqueous	Bovine Base, Liquid	Human serum, Liquid
Bulk Storage	2° to 8°C	-10° to -20°C	-10° to -20°C
Unopened Stability	Until Expiration Date	Until Expiration Date	Until Expiration Date
Open Storage	2° to 8°C	2° to 8°C	2° to 8°C
Open Stability	30 Days	30 Days	15 Days
Container	Plastic, Dropper Tip	Glass	Glass

7. Test Results:

The equivalence for this product was carried out by comparing the inter-assay precision of the listed analytes of the **DOCUMENT**® Ammonia, Ethanol, Lactate Assayed Control to that of CASCO **DOCUMENT**® Ammonia/Ethanol (Protein-Based) Controls and Bio-Rad Liquichek Unassayed Chemistry Controls. The results show that the **DOCUMENT**® Ammonia, Ethanol, Lactate Assayed Control behaves in a similar manner compared to the predicate devices and is suitable for use as a control for the listed analytes.