BIO-RAD **Bio-Rad Laboratories**

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K965171

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510(k) Summary

Submitter
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Date of Summary Preparation
December 19, 1996

Device (Trade & Common Name)
Liquichek Urinalysis Control

Classification Name
CFR 862.1660: Urinalysis Controls
(Assayed and Unassayed)

Devices to Which Substantial Equivalence is Claimed
Liquid Urine Control
Kenlor Industries
Westminister, CA
K890577

Statement of Intended Use
Liquichek Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of laboratory dipstick and microscopic testing procedures for the analytes listed in the package insert.

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Description of the Device

Liquichek Urinalysis Control is prepared from human urine with added human erythrocytes, leukocytes and constituents of non-human origin and pure chemicals. The control is provided in liquid form for convenience.
Level 2 of this product contains 0.1% sodium azide as a preservative.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

A table is provided below comparing the similarities between the Bio-Rad Liquichek Urinalysis Control and the devices to which substantial equivalence is claimed.

	Bio-Rad Liquichek Urinalysis Control	Liquid Urine Control Kenlor Industries
Intended Use	an assayed quality control urine to monitor the precision of laboratory dipstick and microscopic testing procedures for the analytes listed in the package insert	for monitory the accuracy and precision of dipstick and microscopic analysis
Form	Liquid	Liquid
Matrix	Human Urine	Human Urine
Storage	2-8°C	2-8°C
Open Vial Claim	2-8°C for 30 days or 10 immersions; 18-25°C for 7 days or 10 immersions	2-8°C for 2 weeks or 15 immersions; room temperature for 2 weeks or 10 immersions