



**Bio-Rad
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K 960987

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510(k) Summary

Submitter

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Contact Persons

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Date of Summary Preparation

May 2, 1996

Device (Trade & Common Name)

Liquichek Rheumatoid Factor Control

Classification Name

Class II
CFR 866.5775, Rheumatoid Factor Immunological Test System
82DHR

Devices to Which Substantial Equivalence is Claimed

Liquichek Rheumatoid Factor Control
K923578

Statement of Intended Use

Liquichek Rheumatoid Factor Control is intended for use as an assayed quality control serum to monitor the precision of an individual laboratory's rheumatoid factor testing methodologies.

Description of the Device

Liquichek Rheumatoid Factor Control is prepared from human serum with added constituents of human origin.



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Statement of How Technological Characteristics Compare to Substantial Equivalence Device

A table is provided below comparing the technological characteristics between Liquichek Rheumatoid Factor Control and the original device to which substantial equivalence is claimed.

	Liquichek Rheumatoid Factor Control (original submission)	Liquichek Rheumatoid Factor Control (additional information submitted in 1996)
Intended Use	assayed control for rheumatoid factor testing methodologies	assayed control for rheumatoid factor testing methodologies
Matrix	Human Serum	Human Serum
Product Levels	single level product	trilevel level product (two additional levels added)
Storage	2-8°C	2-8°C