



**Bio-Rad
Laboratories**

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K901828

510(k) Summary

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Submitter

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Date of Summary Preparation

May 8, 1996

Device (Trade & Common Name)

Liquichek Cardiac Markers Control

Classification Name

CFR 862.1660: Quality Control Material
(Assayed and Unassayed)

Devices to Which Substantial Equivalence is Claimed

Liquichek CK/LD Isoenzyme Control
Bio-Rad Laboratories, Anaheim, CA
K903430

Statement of Intended Use

Liquichek Cardiac Markers Control is intended for use as an assayed quality control serum to monitor the precision of an individual laboratory's specific cardiac marker procedures.



Description of the Device

Liquichek Cardiac Markers Control is prepared from human serum with added constituents of human and non-human origin. The control is provided in liquid form for convenience.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

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

	Bio-Rad Liquichek Cardiac Markers Control	Bio-Rad CK/LD Isoenzyme Control
Intended Use	To monitor the precision of a laboratories specific cardiac markers procedures.	To monitor the precision of a laboratories CK (Creatine Kinase), LD (Lactate Dehydrogenase) and serum protein testing procedures.
Form	Liquid	Liquid
Matrix	Human Serum	Human Serum
Storage	-10 to -20°C	-10 to -20°C
Open Vial Claim	20 Days at 2-8°C for all analytes; except Troponin T which is stable for 10 Days at 2-8°C	10 Days at 2-8°C