

K 961807

JUL 26 1996

Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitters Information

Contact person: William J. Pignato
Director of Regulatory Affairs

Address: Chiron Diagnostics Corp.
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Medfield, MA 02052

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Date Summary Prepared: April 25, 1996

2. Device Information

Proprietary Name: Certain® Hct and CVM™ Hct
Common Name: Hematocrit quality control and calibration
verification materials
Classification Name: Quality Control Material (assayed & unassayed
Calibration Verification Material
Classification Number: 21 CFR 862.1660

3. Predicate Device Information

Name: GEM critCheck
Manufacturer: Mallinckrodt
510(k) Number:

4. Device Description

The Chiron Certain Hct is a bi-level quality control material uniquely formulated to provide quality control values for hematocrit analyzers. There are two levels of Certain Hct each provided in 2.5 mL ampules. The product allows verification of analyzer hematocrit performance within established ranges.

Chiron Calibration Vefication Material (CVM™) is formulated to verify the calibration of hematocrit analyzers. The product contains four levels of 2.5 mL ampules and is intended to assist laboratories in compliance with the requirements of calibration verification under CLIA.

5. Statement of Intended Use

The intended use Certain® Hct is as a bi-level quality control material and CVM™ is a calibration verification material both for use with hematocrit analyzers.

6. Summary of Technological Characteristics

Certain® Hct and CVM™ Hct are assayed aqueous based bicarbonate solution and other salts.