K962021

JUN 24 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: Ciba Corning Diagnostics Corp.
63 North Street
Medfield, MA 02052

Phone: 508 359-3825

Date Summary Prepared: May 22, 1996

2. Device Information

Proprietary Name:	Ciba Corning 348 System
Common Name:	Analyzer for Blood Gas, electrolytes and metabolites
Classification Name:	Electrode/Sensor measurement of blood gases, blood pH and blood electrolytes
Classification Number:	Calcium - 21 CFR 862.1145, Class II
	Hematocrit - 21 CFR 864.6348, Class II
	Potassium - 21 CFR 862.1600, Class II
	Sodium - 21 CFR 862.1665, Class II
	*p*CO2 - 21 CFR 862.1120, Class II
	*p*O2 - 21 CFR 862.1120, Class II
	pH - 21 CFR 862.1120, Class II

1. Predicate Device Information

Name:	Model 850 Analyzer
Manufacturer:	Ciba Corning Diagnostics Corp.
510(k) Number:	D.C. # K933373

2. Device Description

The 348 Series system analyzer is a point of care and laboratory testing analyzer used for the direct measure of whole blood samples for the determination of the following parameters:

- partial pressures of carbon dioxide; pCO_2
- partial pressure of oxygen pO_2

- pH
- sodium; Na^+
- potassium; K^+
- ionized calcium; Ca^{++}
- hematocrit; Hct

3. **Statement of Intended Use**

The Ciba Corning 348 System is intended for the point-of-care and laboratory testing of blood gases, electrolytes and metabolites in arterial, venous and capillary whole blood samples.

4. **Summary of Technological Characteristics**

The 348 Series System uses measurement technology that is based on electrochemical phenomena. The device uses potentiometry, amperometry and conductimetric methods to convert the potential generated by the sensor to an electrical signal which the system then converts to a value that represents that concentration of a specific analyte in the whole blood sample.

The 348 Series sensors (i.e., electrodes) provide direct measurement of the specific analytes or substances in the sample. Each sensor in the 348 system is highly selective for one substance over others.

The sensors use the following measurement technology:

Sensor	***Measurement Technology***
pH, Na+, K+, Ca++,	potentiometric method using ion-selective electrode technology
reference	silver electrode in potassium chloride and silver chloride
pCO_2	potentiometric method
$p0_2$	amperometric method
hematocrit	conductimetic method