

K961657

## Summary of Safety and Effectiveness

JUN 25 1996

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

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Date Summary Prepared: April 29, 1996

### 2. Device Information

Proprietary Name: Ciba Corning 400 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
Chloride -	21 CFR 862.1170, Class II
Glucose -	21 CFR 862.1345, Class II
Hematocrit -	21 CFR 864.6400, Class II
Potassium -	21 CFR 862.1600, Class II
Sodium -	21 CFR 862.1665, Class II
pCO <sub>2</sub> -	21 CFR 862.1120, Class II
pO <sub>2</sub> -	21 CFR 862.1120, Class II
pH -	21 CFR 862.1120, Class II

### 1. Predicate Device Information

Name: Model 860 Analyzer  
Manufacturer: Ciba Corning Diagnostics Corp.  
510(k) Number: D.C. # K934907

### 2. Device Description

The 400 Series system analyzer is a point of care and laboratory testing analyzer used to for the direct measure of whole blood samples for the determination of the following parameters:

- partial pressures of carbon dioxide;  $p\text{CO}_2$
- partial pressure of oxygen  $p\text{O}_2$
- pH
- sodium;  $\text{Na}^+$
- potassium;  $\text{K}^+$
- ionized calcium;  $\text{Ca}^{++}$
- chloride;  $\text{Cl}^-$
- glucose
- hematocrit; Hct

### 3. Statement of Intended Use

The Ciba Corning 400 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 400 Series System uses measurement technology that is based on electrochemical phenomena. The device use 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 400 Series sensors (i.e., electrodes) provide direct measurement of the specific analytes or substances in the sample. Each sensor in the 400 system is highly selective for one substances over others.

The sensors employ the use of thick-film hybrid technology and a solid-state design in place of the traditional electrodes that use internal fill solutions that are used in the traditional blood gas/electrolyte systems.

Features the planar-format sensors include:

- Suitability for use with the compact disposable measurement cartridge used with the 400 Series
- Sensors require a small volume of sample (75  $\mu\text{L}$ )
- Sensors are maintenance free

The sensors use the following measurement technology:

<i>Sensor</i>	<i>Measurement Technology</i>
pH, Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup>	potentiometric method using ion-selective electrode technology
reference	silver electrode in potassium chloride and silver chloride
pCO <sub>2</sub>	potentiometric method
pO <sub>2</sub>	amperometric method
glucose	amperometric method using an enzyme electrode that uses glucose oxidase
hematocrit	conductimetric method