SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K200107

B Applicant

Epocal Inc.

C Proprietary and Established Names

epoc® Blood Analysis System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CHL	Class II	21 CFR 862.1120 - Blood Gases (PCO2, PO2) and Blood pH Test System	CH - Clinical Chemistry
CEM	Class II	21 CFR 862.1600 - Potassium test system	CH - Clinical Chemistry
JGS	Class II	21 CFR 862.1665 - Sodium test system	CH - Clinical Chemistry
JFP	Class II	21 CFR 862.1145 - Calcium test system	CH - Clinical Chemistry
JPI	Class II	21 CFR 864.6400 - Hematocrit measuring device	HE - Hematology
CGA	Class II	21 CFR 862.1345 - Glucose test system	CH - Clinical Chemistry
KHP	Class I	21 CFR 862.1450 - Lactic acid test system	CH - Clinical Chemistry
CGL	Class II	21 CFR 862.1225 - Creatinine test system	CH - Clinical Chemistry
CGZ	Class II	21 CFR 862.1170 - Chloride test system	CH - Clinical Chemistry
CDS	Class II	21 CFR 862.1770 - Urea nitrogen test system	CH - Clinical Chemistry

Product Code(s)	Classification	Regulation Section	Panel
JFL	Class II	21 CFR 862.1160 - Bicarbonate/carbon dioxide test system	CH - Clinical Chemistry

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) numbers of the SUBMITTER'S previously cleared device, the epoc® Blood Analysis System, k092849, k093297, k113726, and k171247.

2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATIONS**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This change was for:**

    - Change from the previously cleared epoc® Host (a dedicated-use Personal Digital Assistant (PDA) computer-based platform that operators on Microsoft® Windows Mobile 6.5 Operating System (OS)) to the new epoc® NXS Host (a tablet-based mobile platform running on Android 9.0 OS). These changes include the following:

        - Changes to the epoc® System user manual and Quick Start Guide to add instructions specific for the NXS Host.

        - Change to the epoc® Host Software application (from a Windows-based OS to Android 9 OS), including a new user interface

        - Hardware changes
            - Change in form factor for Cradle (device component that holds the epoc® NXS Host)
            - New mobile computer assembly (change in processors and electronics, battery, and power circuits)
            - Bluetooth and Wi-Fi module
            - New barcode scanner
            - New touchscreen
            - New case surface materials and structural design
            - New MicroSD card
            - New audio component

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

5. A Design Control Activities Summary which includes:

    a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

    b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.