

SPECIAL 510(k): Device Modification
OIR Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER k141829

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.) **k131727, CERA-CHEK I070 Blood Glucose Monitoring System.**
2. Submitter's statement that the **INDICATION/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 **MODIFICATION(S)**, 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 the following items:

- i. Changing the name of the test system: The name of submitter's previously cleared test system (k131727) is the "CERA-CHEK I070 Blood Glucose Monitoring System", while the subject device is called the "GlucoVitaal H1A Blood Glucose Monitoring System". The name of the meter has been changed to "GlucoVitaal H1A Blood Glucose Test Meter"; the name of the test strips have been changed to "GlucoVitaal H1A Blood Glucose Test Strips"; the names of the control solutions have been changed to "GlucoVitaal H1A Glucose Control Solution 1" and "GlucoVitaal H1A Glucose Control Solution 2". The name of the data management system has been changed to the "GlucoVitaal H1A Diabetes Management Software".
 - ii. Making the meter non-coding through modifications to manufacturing specifications specific to the GlucoVitaal H1A BGMS. This also involves a software change to eliminate the code-setting function of the meter.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics (dimensions, weight), device performance and specifications.
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.

The GlucoVitaal H1A Blood Glucose Monitoring System is intended for single patient use. Disinfection efficacy studies were performed for the predicate device (k131727, CERA-CHEK 1070 Blood Glucose Monitoring System) by an outside commercial testing laboratory and demonstrated complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Metrex Research Corporation Caviwipes (EPA Registration # 46781-8). Robustness studies also performed for the predicate device demonstrated that there was no change in performance or external materials of the meter after 1825 cleanings and 1825 disinfection steps with Metrex Research Corporation Caviwipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.