

SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K222234

B Applicant

Apex BioTechnology Corp.

C Proprietary and Established Names

GlucoSure ADVANCE Link Blood Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose 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) number of the SUBMITTER'S previously cleared device.

BGM014 Blood Glucose Monitoring System, K161299
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 **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**. The modifications are listed below:

- Bluetooth Low Energy (BLE) connectivity was added to the meter along with the associated addition of the Bluetooth icon to the meter display and the addition of Bluetooth related error messages.
 - The color of the test strip ejection button was changed from gray to white and the color on the backside of the meter display cover was changed from grey to blue.
 - The control solution test process was changed from 4 steps to 3 steps.
 - The meter memory was decreased from 1000 to 700 test results.
 - The battery life claim was decreased from 1000 tests to 750 tests.
 - The device system name was changed from BGM014 Blood Glucose Monitoring System to GlucoSure ADVANCE Link Blood Glucose Monitoring System.
 - The meter name was changed from BGM014 Blood Glucose Meter to GlucoSure ADVANCE Link Blood Glucose Meter.
 - The test strip name was changed from BGM014 Blood Glucose Test Strips to GlucoSure ADVANCE Link Blood Glucose Test Strips.
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.

The device system is intended for single patient use only. Disinfection efficacy studies were previously performed on the exterior meter materials by outside testing laboratories demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant products including: Dispatch® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg#56392-8) (K113098, K143750), Clorox Healthcare® Bleach Germicidal and Disinfectant Wipes (EPA#67619-12) (K131750), Medline Micro-Kill+™ Bleach Germicidal Bleach Wipes (EPA#69687-1-37549) (K150396), Medline Micro-Kill+™ Disinfecting, Deodorizing, Cleaning Wipes with Alcohol (EPA#59894-10) (K150396, K143750), and Super Sani-Cloth® Germicidal Disposal Wipe (EPA#9480-4) (K182992). Robustness studies were also previously performed by

the sponsor (K161299 and K182992) demonstrating that there was no change in performance or external materials of the meter after 1825 cleaning and disinfection cycles with the chosen wipes described above. The robustness studies were designed to support 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.