

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

**To:** THE FILE

**RE:** DOCUMENT NUMBER k122110

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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 for the **On Call Vivid Pal Blood Glucose Monitoring System**:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. **On Call Vivid Blood Glucose Monitoring System k112653**
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:**

- Change in meter physical dimensions from 89.6mmX58.0mmX21.7mm to 75mmX40mmX13mm (LxWxH) and meter weight 35.5g (with batteries installed)
  - Battery Type from two CR 2032 3.0 V coin cell batteries (one for testing and the other one for display backlight and strip port light) to one CR 2032 3.0 V coin cell battery
  - Removed meter display backlight and strip port light
  - Removed test strip ejector from meter
  - Change in PCB configuration from two layers to four layers
  - Three buttons moved to a different location from X to Y
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and cleaning, disinfection, and robustness study.
  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
    - c) A declaration of conformity with design controls. The declaration of conformity should include:
      - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

**6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

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.

This On Call Vivid Pal Blood Glucose Monitoring System is intended for single-patient home use. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, (DisCide Wipes) Quaternary Ammonium/Isopropyl Alcohol disinfectant wipe (EPA Reg. No. 10492-4). Robustness studies were also performed by the sponsor demonstrating that there was not change in performance or external materials of the meter and lancing device after 1,825 times of cleaning and disinfection cycles, using (DisCide Wipes) Quaternary Ammonium/Isopropyl Alcohol disinfectant wipes, to simulate 5 years of use by layusers. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.