

SPECIAL 510(K): DEVICE MODIFICATION OIR DECISION SUMMARY

510(k) Number: k180196

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.)

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 the following items:

- a. The name has changed from On Call Express Blood Glucose Monitoring System to On Call Express Mobile Blood Glucose Monitoring System
 - b. Addition of a Bluetooth module for the wireless transfer of data to mobile devices.
 - c. Meter display has been changed to accommodate new housing and Bluetooth function.
 - d. The housing of the On Call Express Blood Glucose monitoring system has been changed. Since the Bluetooth function is introduced RS232 phone jack port (for data download to PC) has been removed.
 - e. Strip ejector has been removed.
 - f. The Hematocrit range of the meter is expanded from 30-55% to 25-60%.
 - g. Battery the battery life of the meter has been changed from 1,000 measurements to 500 Measurement.
 - h. The memory is increased from 300 records with time date to 500 records with time and date.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, 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 On Call Express Mobile Blood Glucose Monitoring System is intended for single-patient home use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of viral hepatitis B virus (HBV) with the chosen disinfectant, DisCide Ultra Disinfecting Towelettes (EPA Reg. No: 10492-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 260 cleaning and disinfection cycles designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.