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

To: THE FILE **RE:** DOCUMENT NUMBER **k120448**

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.) **k101204 MEG-2 and MEG-2 Multi 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:

A. The new MEG-2B and MEG-2B Pro systems use a modified test strip and test strip holder relative to the predicate MEG-2 and MEG-2 Multi systems.

   The changes are:

   - Width of the strip holder (8mm to 6mm)
   - Size of test strip (from 18x8x0.4 mm to 38x6x0.4 mm)
   - Dimension of sample channel: from 1.4Wx3.4Lx0.15H (mm) to 1.4W x 3.4Lx 0.135H (mm)
   - Sample size: from >1ul to ≥0.8ul

B. The new MEG-2B and MEG-2B Pro meters use the same basic measurement algorithm as the predicate meters, but the software has been modified to function with the modified test strip holder and test strip which use a 7-code system instead of the predicate 4-code system.

C. The new MEG-2B and MEG-2B Pro systems use modified control solutions. The new MEG-2B control solutions have the same chemical components (including a red dye) as the predicate MEG-2 control solutions, but have slightly different glucose levels. Otherwise the formulation is identical.

D. Altitude limitation from 6560 feet to 10335 feet.
   The MEG-2B strip is identical to the GAL-1C strip previously cleared in the GAL-1C BGMS in k102816. The altitude study in k102816 supported the altitude limitation of 10335 feet.

E. The name of the device has changed from "**MEG-2 and MEG-2 Multi Blood Glucose Monitoring System**" to "**MEG-2B and MEG-2B Pro Blood Glucose Monitoring System**"

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and analytes.

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.

The device system is intended for single-patient (MEG-2B) or multiple-patient use (MEG-2B Pro). Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Dispatch Hospital Cleaner Disinfectant Towels with Bleach disposable wipes (EPA Reg. No: 56392-8). The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 1,825 cleaning and disinfection cycles to simulate 5 years of use by lay-users and after 10,950 cleaning and disinfection cycles to simulate 3 years of multiple-patient use.