SPECIAL 510(k): Device Modification
OIR Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K123087

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.) **Tyson Bio AC100 Blood Glucose Monitoring System (k101543).**

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

   - **Name changes from TysonBio AC100 Blood Glucose Monitoring system to TysonBio AC500, AC500 Pro, AC800 and AC800 Pro Blood Glucose Monitoring Systems**
   - **Minor outer design changes include:**
     - **Operational button shape and position,**
     - **Embedded color changes of casing and buttons**
     - **Oval shape verses egg shape**
   - **The addition of a backlit display on the AC800 models**
   - **Remove voice function from AC500 models**
   - **The hematocrit range change to 20% - 60% from 35-55% utilizing a modification in the applied voltage pulse frequency specifications, while using the same the final stage signal voltage and amperometric method.**

4. **Comparison Information** (similarities and differences) to applicant'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
   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 validation protocols were adequate to address the identified causes of hazards identified in the Risk analysis (FMEA).

The devices consist of both single-patient use and multiple-patient use. . Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Cavicide Surface Disinfectant (EPA Registration #46781-6). Robustness studies were also performed by the sponsor demonstrated that there was no change in performance or in the external materials of the meter after 36500 cleaning and disinfection cycles, using Cavicide Surface Disinfectant designed to simulate cleaning and disinfection 20 times a day, over 5 years of device use. The sponsor also demonstrated that there was no change in performance or in the external materials of the lancing device for single-patient use after 7300 cleaning and disinfection cycles designed to simulate cleaning and disinfection 4 times a day, over 5 years of device use. Labeling has been reviewed for adequate instructions for the validated cleaning and disinfection procedures.