SPECIAL 510(k): Device Modification
OIR Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K161834

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): **One Drop Blood Glucose Monitoring System**

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.) **AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System (k152365)**
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:

   1. Name of the device system was changed from Agamatrix Jazz Wireless 2 Blood Glucose Monitoring System to One Drop Blood Glucose Monitoring System.
   2. The meter length was increased by 0.2 inches to 2.76 inches and meter width increased by 0.08 inches to 0.47 inches.
   3. The meter weight was increased by 2 grams
   4. The meter housing material was changed from an ABS polymer blend with color pigment added to ABS polymer blend covered with aluminum plating

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics (including efficacy of cleaning and disinfection agents on the materials of the meter and robustness of the system to repeated cleaning and disinfection).
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 One Drop Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were performed on materials comprising the meter demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfecting agent, PDI Super Sani-Cloth® Germicidal Disposable Wipe (EPA Registration #9480-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 520 cleaning and disinfection cycles with PDI Super Sani-Cloth® Germicidal Disposable Wipe (EPA Registration #9480-4). The robustness studies were designed to simulate 5 years of single-

patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to the finalization of the guidance documents.