SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE RE: DOCUMENT NUMBER k153201

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.)

   SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System and SD GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System (k132929)

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 addition of Bluetooth for wireless transmission of data to a mobile device.

   b. Memory capacity for stored glucose test results decreased from 300 to 100 records.

   c. The trade name of the systems has changed from SD GlucoNavii Mentor NFC Blood Glucose Monitoring System and SD GlucoNavii Mentor NFC Multi Blood Glucose Monitoring System to SD GlucoNavii Mentor BT Blood Glucose Monitoring System and SD GlucoNavii Mentor BT Multi Blood Glucose Monitoring System.

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 SD GlucoNavii Mentor BT Blood Glucose Monitoring System is intended for single-patient use.
The SD GlucoNavii Mentor BT Multi Blood Glucose Monitoring System is intended for multiple-patient use in a professional healthcare setting. There were no physical changes to the subject device relative to the predicate that would warrant new disinfection efficacy studies. Disinfection efficacy studies were performed on the materials comprising the meter for the predicate device (k132929) by an outside

commercial testing laboratory and demonstrated complete inactivation of Hepatitis B Virus (HBV) with the chosen disinfectant, Discide Ultra Disinfecting towlettes (EPA Registration No. 10492-4). Robustness studies were performed on the subject device to demonstrate that there were no changes in performance or external materials of the meter after 10,950 cleanings and 10,950 disinfection steps with Discide Ultra Disinfecting towlettes. The robustness studies were designed to simulate 3 years of multi-patient use and 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.