SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K163490

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.) **Statstrip Xpress 2 Glucose Hospital Meter System - k152986**
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:

   - Changing the lower limit of the operating temperature range from 59°F (15°C) to 41°F (5°C)
   - Modifying the software for the temperature error code from displaying the error when the operating temperature is less than 15°C to displaying the error when th operating temperature is less than 5°C.

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

Infection Control Studies:
The StatStrip Xpress 2 Glucose Hospital Meter System is intended for multiple-patient use. Disinfection efficacy studies were previously performed (k150461) on the external materials of the meter by an outside commercial testing service and demonstrated complete inactivation of live Hepatitis B virus with Clorox Germicidal Wipes, EPA registration # 67619-12). The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 3 years of device 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).