

SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE

RE: DOCUMENT NUMBER K152986

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.) **K150461, StatStrip Xpress Glucose Hospital Meter 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:

- 1) Meter screen display has changed from a segmented display to a 2.2 inches color graphics display.
 - 2) The battery used in the device has changed from a single Li 2450 coin cell battery to two AAA batteries.
 - 3) Modified ergonomic design to a flat, top surface design that eliminates ridges, recessed corners and raised edges of the predicate device.
 - 4) Modified button shape and position.
 - 5) Moved the test strip port from the top of the meter to the bottom of the meter.
 - 6) Minor change in the software to incorporate color into the interface of the StatStrip Xpress 2 Glucose Hospital Meter.
 - 7) Name change of the system name from StatStrip Xpress Glucose Hospital Meter System to StatStrip Xpress 2 Glucose Hospital Meter System.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics. **Studies performed include meter robustness studies, human factor / usability study, and the CLIA waiver Precision and Method Comparison studies.**
 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 device system is intended for multiple-patient use. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Germicidal Disposable Wipes (EPA Registration # 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter and lancing device after 10950 cleanings and 10950 disinfection steps with the 10905 wipes. The robustness studies were designed to simulate 3 years of multiple-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.