

SPECIAL 510(k): Device Modification OIR Review Summary

To: THE FILE

RE: DOCUMENT NUMBER K150396

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.) **K102037, AutoSure Voice II Blood Glucose Monitoring 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 the following items:
 - a. The trade name of the meter has changed from AutoSure Voice II Blood Glucose Monitoring System to the AutoSure Voice II Blood Glucose Monitoring System (for self-testing) and AutoSure Voice II Pro Blood Glucose Monitoring System (for multiple-patient use)
 - b. Addition of validated cleaning and disinfection instructions to the labeling for both the AutoSure Voice II and AutoSure Voice II Pro Blood Glucose Monitoring Systems
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and device performance and specifications
5. **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 sponsor has added validated cleaning and disinfection instructions to the labeling for the self-testing system, the AutoSure Voice II Blood Glucose Monitoring System. Disinfection efficacy studies were performed on the materials comprising the meter by outside commercial testing laboratories demonstrating complete inactivation of hepatitis B virus (HBV) or removal of HBsAg with the following disinfectants: Clorox Healthcare Bleach Germicidal and Disinfectant Wipes (EPA Registration Number: 67619-12), Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Registration Number: 56392-8), Medline Micro-Kill+ Disinfecting, Deodorizing, Cleaning Wipes with Alcohol (EPA Registration

Number: 59894-10), and Medline Micro-Kill Bleach Germicidal Bleach Wipes (EPA Registration Number: 69687-1-37549). Each of these disinfectants was validated separately for use with the meter.

Robustness studies were also performed separately for the four disinfectants listed above, demonstrating that there was no change in performance or external materials of the meter following 1825 cleaning and disinfection cycles. The robustness studies were designed to simulate five years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

The sponsor has also added validated cleaning and disinfection instructions to the labeling for the multiple-patient use system, the AutoSure Voice II Pro Blood Glucose Monitoring System. Disinfection efficacy studies were performed on the materials comprising the meter by outside commercial testing laboratories demonstrating complete inactivation of hepatitis B virus (HBV) or removal of HBsAg with the same four disinfectants listed above. Each of these disinfectants was validated separately for use with the meter. Robustness studies were also performed separately for the four disinfectants listed above, demonstrating that there was no change in performance or external materials of the meter following 10,950 cleaning and disinfection cycles. The robustness studies were designed to simulate three years of multiple-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.