

SPECIAL 510(k): Device Modification
OIVD Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER k101543

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:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (k090629 - Easy Step, Diachex+ PRO 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.
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:
Addition of optional voice function (for TysonBio AC100/AC100 Pro only) not intended for users with impaired vision, hypoglycemic and hyperglycemic alarm setting, removal of back light feature, modification of outer case appearance, addition of meter voltage error and strip coding error, change in power supply from one CR-2032 to two AAA batteries, and coding change from fixed code to auto coding.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including labeling, intended use, and physical characteristics.
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
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices)**.

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 is intended for single (AC100 and AC200) and multiple (AC100 Pro and AC200 Pro) patient use. **Cavicide Surface Disinfectant** with EPA registration # 46781-6 was validated demonstrating complete inactivation of live hepatitis B virus for use with the meter and lancing device that the sponsor markets for use with the single-patient use blood glucose monitoring systems. The sponsor demonstrated that there was no change in performance or in the external materials of the meter after 36500 cleaning and disinfection cycles designed to simulate cleaning and disinfection 20 times a day, over 5 years of device use. The sponsor also demonstrated that there was no change in performance or in the external materials of the lancing device for single-patient use after 7300 cleaning and disinfection cycles designed to simulate cleaning and disinfection 4 times a day, over 5 years of device use. In addition, the sponsor provided a risk analysis specific to the potential harm due to infection. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.