

SPECIAL 510(k): Device Modification

OIVD Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER: **k102345**

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.)
EPS Bio Technology Corporation, EasyMax N Self Monitoring Blood Glucose System - k083099.
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:
 - A. The physical appearance of the meter has changed.
 - B. The two button (M and S) functions are removed.
 - C. The trade name of the meter has changed from EasyMax N to EasyMax T1.
 - D. The memory function has changed from "a memory capacity of 480 test results" to "no memory capacity".
 - E. The power supply source changed from "two alkaline 1.5V batteries" to "two CR2032 batteries".
 - F. Print circuit board has changed.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and performance 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 – risk analysis was FMEA.
 - 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.

Reviewer's Comments:

The device is intended for single patient home use (EasyMax T1 Self Monitoring Blood Glucose System) and multiple patient use in a professional healthcare settings (EasyMax T1 Pro Self Monitoring Blood Glucose System). PDI® SUPER SANI-CLOTH® Germicidal disposable wipes (EPA Reg. No: 9480-4) was validated demonstrating complete inactivation of live virus for use with the meter and lancing device. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 11,000 cleaning/disinfection cycles (each cleaning/disinfection cycle includes 11,000 pre-cleaning and 11,000 disinfection wipes adding up to a total of 22, 000 wipes) designed to simulate 3 years (EasyMax T1 Pro Self Monitoring Blood Glucose System) and 4 years (EasyMax T1 Self Monitoring Blood Glucose System) of device use. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.