

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

k070941

B. Purpose for Submission:

Addition of software allowing data transfer and viewing from device to personal computer.

C. Manufacturer and Instrument Name:

TaiDoc Technology Corporation, CLEVER CHEK Health Care System Software

D. Type of Test or Tests Performed:

This device does not directly test glucose. This is an accessory to previously cleared TaiDoc glucose and glucose/blood pressure monitors (k061181, k062235, k063212, k070239, k070472, k062800, k070641, k051703).

E. System Descriptions:

1. Device Description:

The Clever Chek Health Care System Software is an optional software accessory for use with the following models with data management capabilities: a) Clever Chek blood glucose meters, b) Clever Chek blood glucose plus blood pressure monitors, and c) Clever blood pressure monitors. When used with one of these meters, Clever Chek Health Care System Software transfers data from the device's memory into a computer for enhanced data management.

2. Principles of Operation:

The Clever Chek Health Care System Software provides users the ability to export data from compatible TaiDoc meters to a computer via a cable connecting to the computer's required 9-pin (RS232) port. The export of the data allows the data to be viewed only in the Clever Chek software. Aside from the ability to export the data stored in the meter's memory, the software also allows the setting of the meter's time and the ability to clear the meter's memory.

3. Modes of Operation:

Wired data transfer of stored glucose and blood pressure measurements as well as setting of time and memory clearing on the meter.

4. Specimen Identification:

For an example, see k062800.

5. Specimen Sampling and Handling:

For an example, see k062800.

6. Calibration:
For an example, see k062800.
7. Quality Control:
For an example, see k062800.
8. Software:
FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:
Yes___X___ or No_____

F. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Glucose Test System
21 CFR § 870.1130, Noninvasive blood pressure measurement system
2. Classification:
Class II
3. Product code:
NBW
DXN
4. Panel:
75 (Clinical Chemistry)
74 (Cardiovascular)

G. Intended Use:

1. Indication(s) for Use:
The Clever Chek Health Care System Software is an optional software accessory for use with the following models with data management capabilities: a) Clever Chek blood glucose meters, b) Clever Chek blood glucose plus blood pressure monitors, and c) Clever blood pressure monitors. When used with one of these meters, Clever Chek Health Care System Software transfers data from the device's memory into a computer for enhanced data management.

The Clever Chek Health Care System Software is intended for use in home and clinical settings as an aid for users and their health care professionals to review, analyze and evaluate the historical test results to support health management effectively.

2. Special Conditions for Use Statement(s):
None.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
Camit Diabetes Management Software, k001907

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	Same intended use	Same intended use
Data Use	Data transferred from the device cannot be changed or modified.	Same

Differences		
Item	Device	Predicate
Meter Compatibility	For use with TaiDoc meters	For use with Roche meters

I. Special Control/Guidance Document Referenced (if applicable):

- 1) Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- 2) IEC 601-1-4, Safety Requirements for Programmable Electronic Medical Systems
- 3) EN 60601-1-4, Medical electrical equipment part 1-4: general requirements for safety – collateral standard: Programmable electrical medical systems

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

The sponsor validated overall software usage and data transfer functionality. Software usage validation entailed testing each of the software's design requirements to ensure that they were met. Data transfer was tested by transferring sets of data (from both the glucose and blood pressure aspects of the device) from the meter to the software and checking that the data was downloaded in its entirety, was able to be viewed and graphed by the software, and that the data points (measurement results and time tested) that were transferred to the software matched the original data taken from the meter.

For an example of performance of the glucose meter, strips, and blood pressure monitor, see k062800.

b. Precision/Reproducibility:

For an example of performance of the glucose meter, strips, and blood pressure monitor, see k062800.

c. Linearity:

For an example of performance of the glucose meter, strips, and blood

pressure monitor, see k062800.

d. Carryover:

For an example of performance of the glucose meter, strips, and blood pressure monitor, see k062800.

e. Interfering Substances:

For an example of performance of the glucose meter, strips, and blood pressure monitor, see k062800.

2. Other Supportive Instrument Performance Data Not Covered Above:

None.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.