

SPECIAL 510(k): Device Modification OIR Decision Summary

To: THE FILE

RE: DOCUMENT NUMBER k170614

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.)

NoCoding1 Plus Blood Glucose Monitoring System (k160742)

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:

The two meters in this submission are identical except for the name and the addition of Bluetooth to one of the meters

- a. The trade name was changed from NoCoding1 Plus Blood Glucose Monitoring System to CareSens N Premier Blood Glucose Monitoring System and CareSens N Premier BT Blood Glucose Monitoring System
 - b. The meter shell color was changed from white to black (upper case) and light gray to black (lower case)
 - c. Button positioning was changed from the sides to the front of the meter
 - d. The material of the buttons was changed from Polycarbonate (PC) to Silicone Rubber and color changed from gray to black
 - e. The material of the meter screen was changed from PC to Acrylic
 - f. The material of the foot of the meter changed from Thermoplastic Polyurethane (TPU) to Thermoplastic elastomer (TPE)
 - g. Addition of a test strip ejection button
 - h. Addition of backlight capability to the LCD
 - i. Addition of a Bluetooth module to the CareSens N Premier BT Blood Glucose Monitoring System for the wireless transfer of data to mobile devices
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and specifications.
 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 CareSens N Premier Blood Glucose Monitoring System and the CareSens N Premier BT Blood Glucose Monitoring System are intended for single patient home use. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial laboratory testing services demonstrating complete inactivation of hepatitis B Virus (HBV) with Clorox Germicidal Wipe (EPA Reg. No: 67619-12). The sponsor also conducted robustness studies and demonstrated that there was no change in performance or in the external materials of the meter after 260 cleaning and disinfection cycles representing 5 years of single patient use. Each robustness cycle tested consisted of one pre-clean wipe and one disinfecting wipe. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.