SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K201551

B Applicant

i-SENS, Inc.

C Proprietary and Established Names

KetoSens BT β-Ketone Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JIN	Class I, meets the limitation of exemption 21 CFR 862.9(c)(5)	21 CFR 862.1435 - Ketones (Nonquantitative) Test System	CH - Clinical Chemistry

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS I device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. The KetoSens Blood β-Ketone Monitoring System, k170463.

2. Submitter's statement that the **INDICATIONS FOR USE/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).

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 addition of bluetooth low energy (BLE) wireless communication capability to the meter
- A change in battery lifetime from 3,000 measurements to 1,000 measurements.
- The addition of Bluetooth icon to meter display and an error code related to the Bluetooth communication
- A change in the system name from KetoSens Blood β-Ketone Monitoring System to KetoSens BT Blood β-Ketone Monitoring System

3. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

4. 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 KetoSens BT Blood β-Ketone Monitoring System is intended for single-patient use. Disinfection efficacy studies were previously performed (k170463) on the materials comprising the meters by an outside commercial laboratory service to demonstrate complete inactivation of hepatitis B virus (HBV) with Clorox Healthcare Bleach Germicidal Wipes (EPA Reg. No. 67619-12). Robustness studies were performed by the sponsor demonstrating that there were no changes in performance or to the external materials of the meter after 260 cleaning and disinfection cycles with Clorox Healthcare Bleach Germicidal Wipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.