CLIA Waiver by Application Approval Determination

Decision Summary

A. Document Number

CW230022

B. Parent Document Number

K083184

C. CLIA Waiver Type:

CLIA Waiver by Application

D. Applicant

Trukera Medical

E. Proprietary and Established Names

ScoutPro Osmolarity System

F. Measurand (analyte)

Tear osmolarity

G. Sample Type(s)

Human tears

H. Type of Test

Quantitative, electrical impedance measurement

I. Test System Description

1. Overview

The device consists of the following components and accessories: Scoutpro Pen with integrated display, Scoutpro charging base, Osmolarity test card, Control Solutions, and Electronic check cards. The Osmolarity Test Card, in conjunction with the ScoutPro Osmolarity System, provides a method for determining tear osmolarity using nanoliter (nL) volumes of tear fluid collected directly from the eyelid margin.

To perform a test, a new Test Card containing a microfluidic capillary channel is attached onto the Pen. The Pen will beep and the green light will illuminate when the Card is attached properly. The user then sets the Test Card Code by using the up/down buttons on the pen so that it matches the Test Card Code on the Test Card. After removing the protective cover, the tip of the Test Card is touched to the inferior tear meniscus located above the lower eyelid and collects 40-50 nanoliters of tear fluid by passive capillary action. The Pen will beep and the green light will turn off after a successful tear collection. The test result will be displayed in a few seconds after successful tear collection, along with the units (mOsm/L).

This device was previously cleared as the OcuSense, Inc. TearLab Osmolarity System under k083184 and was CLIA waived under k083184/A004. The current submission is for device modifications that include moving the display and up/down buttons from the charging base to the pen used to collect the tear sample. Modifications to the labeling include updates to the procedure section instructing the user to adjust the Test Card Code and review the results on the display incorporated into the pen rather than on the base as in the previous version of the device.

To support that the modified device continues to meet the CLIA statutory criteria for waiver, a labeling review was performed and it was concluded that the device continues to pose no unreasonable risk of harm to the patient if performed incorrectly, as compared to the previously waived device.

2. Test System Components

The ScoutPro Osmolarity System contains the following components:

Included

- ScoutPro Pen
- Charging Base
- Set of two Electronic Check Cards

Sold separately

- Osmolarity Test Cards
- Osmolarity Control Solutions

J. Labeling for Waived Devices

The labeling consists of:

1. ScoutPro Osmolarity System User Manual
2. ScoutPro Quick Reference Guide

The following elements are appropriately presented:

- The User's Manual and Quick Reference Guide identify the test as CLIA waived.
- The User's Manual contains a statement that a Certificate of Waiver is required to perform the test in a waived setting.
- The User's Manual and Quick Reference Guide contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1).
- The User's Manual and Quick Reference Guide provide instructions for conducting quality control procedures.
- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

K. Conclusion:

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.