

SureStep®Flexx Blood Glucose Monitoring System CLIA Waiver Status and Clearance for Professional Use

Background Information

The Clinical Laboratory Improvement Amendments (CLIA) law of 1988 specified that laboratory requirements be based on the complexity of the test performed. In the Food and Drug Administration (FDA) Regulations (42 CFR part 493), waived tests were defined as simple laboratory examinations and procedures that are cleared by the FDA for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk or harm to the patient if the test is performed incorrectly.

The regulation states that glucose monitoring devices cleared by the FDA specifically for home use have waived status. Professional use versions of home use tests are not automatically waived but do qualify for expedited waiver review. The differences between the versions are examined by the FDA to determine if a professional use version qualifies for waiver.

Regulatory Status of SureStep®Flexx Blood Glucose Monitoring System (BGMS)

The SureStep®Flexx BGMS is FDA cleared for home use as well as professional use and is categorized as a waived test. This information can be found in CLIA record *K023194* with corresponding 510(K) Premarket Notification information. The 510(K) number for the SureStep®Flexx BGMS is *K023194*. The CLIA Waiver status is found in the “Complexity” section of the CLIA record. The clearance for professional use is found in the 510(K) summary in the section titled “Intended Use”. The Intended Use statement is as follows:

“The SureStep®Pro and the SureStep®Flexx Professional Blood Glucose Management Systems are for *in vitro* diagnostic use for the quantitative measurement of glucose in venous, capillary, arterial, and neonatal whole blood samples. These systems can also be used by lay users at home.”

Note: The BGMS should **not** be used for the diagnosis of diabetes. It can be used as a definitive test to make clinical treatment decisions in the monitoring of blood glucose levels.

The CLIA record *K023194* and corresponding 510(k) Premarket Notification summary is available on the following FDA website: www.fda.gov/cdrh/cli/cliawaived.html

- Scroll down to the bottom of the web page and select the link to the “List of Tests Waived by the FDA”
- Find the CLIA record for the SureStep®Flexx® BGMS by:
 - Selecting the “Edit” menu on the internet browser toolbar
 - Then selecting “Find (on This Page)”
 - Type in SureStep Flexx
- To access the 510(K) summary that contains the “Intended Use” information, click on the “Summary” link in the CLIA record.

References

- Information on CLIA Waivers – www.fda.gov/cdrh/cli/cliawaived.html
- 510(K) Premarket Notification summary for the LifeScan SureStep®Flexx Blood Glucose Monitoring System (K023194) - <http://www.fda.gov/cdrh/pdf2/k023194.pdf>
- JCAHO FAQs: Waived Testing – Screening versus Definitive, April 1, 2005.