510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K192785

B Applicant

Optiscan Biomedical Corporation

C Proprietary and Established Names

OptiScanner® 5000 Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LZF	Class II	21 CFR 880.5725 - Infusion Pump	General Hospital
PYV	Class II	21 CFR 862.1345 - Glucose test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

The purpose of this submission is to add selected peripherally inserted central catheters (PICCs) to the list of catheters which are compatible with the device.

B Measurand:

Plasma glucose from central venous catheter blood draw

C Type of Test:

Quantitative, mid-infrared (MIR) spectrophotometric assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The OptiScanner® 5000 Glucose Monitoring System is an automated, bedside glucose monitoring device indicated for detecting trends and tracking patterns in persons (age 18 and older) in the surgical intensive care unit. The system collects a venous whole blood sample via connection to a central venous catheter, centrifuges the sample, and measures the plasma glucose concentration. It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia. The OptiScanner® 5000 Glucose Monitoring System is for in vitro diagnostic use.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Contraindications:
- Patients that are <18 years of age
- Women who are pregnant or nursing
- Patients undergoing Magnetic Resonance Imaging (MRI) or Computerized Tomography (CT)

Warnings:
- The OptiScanner disposable cartridge should be used only by medical personnel having specific training in, and understanding of, the techniques associated with such devices and procedures.
- The disposable cartridge is for single patient use only. Do not re-sterilize. Do not re-use. Re-use of the cartridge may pose infection to the patient due to non-sterile condition and cross contamination of blood.
- Do not use the cartridge if the packaging is received open or damaged.
- The OptiScanner has not been tested for use in the operating room.
- The OptiScanner should be connected to the most proximal port when using a Central Venous Catheter (this includes pheripherally inserted centeral catheters). If the most proximal port is not available, use next most proximal port for OptiScanner primary connection.- Do not infuse anything above the OptiScanner primary connection.
- Do not rest containers of liquids on top of the OptiScanner enclosure.
- Avoid infusion of any glucose containing solutions adjacent to the OptiScanner port. Infuse these solutions in the most distal port available, as clinical research has shown glucose administered through the distal port does not affect OptiScanner accuracy.
- Be advised of possible complications associated with central venous catheterization. These include but are not limited to: vessel wall perforation, cardiac tamponade, air embolism, catheter embolism, thrombosis, bacteremia, septicemia.

- Due to the risk of further blood loss, do not use the OptiScanner in patients with low hematocrit (less than 15%).
- The OptiScanner should not be used concomitantly with the intravenous administration of high dose ascorbate (IVC) for the treatment of patients with cancer.
- Use caution when OptiScanner readings are below 60 and above 300 mg/dL as these concentrations have not been studied in the intended use population.
- Use caution when OptiScanner is reading in the hypoglycemic range (<70 mg/dL). The comparator measurement check may not be sufficient to indicate instances of severe hypoglycemia, especially when the Low Glucose Alarm is set to 80 mg/dL.
- Though line occlusions were not studied in the trial, it should be noted that the catheters utilized with the OptiScanner may become occluded. In the event of a line occlusion, follow hospital protocol to clear the line.
- Certain substances should be used with caution with the OptiScanner. Refer to the Interfering Substance section in Chapter 7 for more information.
- Not all substances which could potentially interfere with OptiScanner measurement accuracy have been identified. Following the instructions regarding the daily reference check is imperative to screen for potential offsets.
- No additives of any kind are to be passed through or injected into the saline bag or saline flush line.
- Do not use the OptiScanner in patients that are being administered intravenous immunoglobulin therapies (IVIG). These therapies may generate false glucose measurements. Examples of IVIG therapies are Gamimune N, HepaGam B, Octagam, Vaccinia Immune Globulin, and WinRho SDF Liquid.
- Do not use the OptiScanner in patients that have used peritoneal dialysis solutions any time in the past week. These solutions may generate false glucose measurements.
- Do not inject heparin or any other substances into the saline bag.
- If moving the OptiScanner without disconnecting from the patient, always maintain the connection between the venous line and the OptiScanner patient line.
- Do not use stopcocks. Ensure catheter lines are not pinched off by clamps, hemostats or physically kinked.
- Use of stopcocks or catheters with valves (for example, Groshong catheters) that potentially alter, restrict or impede flow should never be used with the OptiScanner.
- Only use normal, 0.9% saline with the OptiScanner. Do not use saline with dextrose, ringers, or any other substance or additive to connect to the OptiScanner.
- The disposable cartridge must be primed before being connected to the patient. Do NOT connect to patient until priming is complete.
- Be sure there is no air in the catheter lumen when connecting the OptiScanner to the patient. If present, air could be returned to the patient. Ensure catheter is primed per manufacturer's instructions for use.

D Special Instrument Requirements:

OptiScanner® 5000 Instrument

IV Device/System Characteristics:

A Device Description:

The OptiScanner® 5000 Glucose Monitoring System is comprised of the OptiScanner® 5000 Instrument, a transportation cart, disposable OptiScanner® cartridges (sold separately), and a barcode scanner with USB connectivity. The OptiScanner® 5000 instrument houses the mechanisms that automatically draw and return blood to the patient, analyzes the sample and calculates the glucose value. The disposable cartridges are sterile, single use only, and designed for use on a single patient for up to 72 hours.

B Principle of Operation:

The OptiScanner® 5000 Glucose Monitoring System samples and measure blood glucose levels every 15 minutes. Samples (~ 3 mL) are drawn from the patients central venous catheter (CVC), multi-lumen access catheter, or peripherally inserted central catheter (PICC). Of the withdrawn blood, 0.17 mL is retained for measurement and the remaining blood is returned to the patient. The retained volume is heparinized to prevent clotting while it is processed and is centrifuged to separate the red blood cells from the plasma. The plasma is evaluated and the glucose quantified by the spectrophotometer by analyzing mid-infrared (MIR) light (7 um – 10 um wavelength) absorption spectra through an array of optical filters. The OptiScanner® 5000 Glucose Monitoring System is designed to display glucose values every 15 minutes along with a trend line with settable high and low alarms.

C Instrument Description Information:

Modes of Operation	**Yes**	**No**
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   OptiScanner® 5000 Glucose Monitoring System

2. Specimen Identification:

   The patient ID can be entered into the OptiScanner® 5000 Glucose Monitoring System manually or by using the barcode scanner included with the system. The patient ID is displayed on the device screen along with the glucose measurement and glucose trend information.

3. Specimen Sampling and Handling:

   The venous blood drawn from the patient for measurement is immediately centrifuged in the disposable test cartridge to plasma and analyzed by the device.

4. Calibration:

   The OptiScanner® 5000 requires no calibration by the user.

5. Quality Control:

   There is no quality control material for use with the OptiScanner® 5000 Glucose Monitoring System.

V Substantial Equivalence Information:

A Predicate Device Name(s):

OptiScanner 5000 Glucose Monitoring System

B Predicate 510(k) Number(s):

K162042

C Comparison with Predicate(s):

Device & Predicate Device(s):	K192785	K162042
Device Trade Name	OptiScanner® 5000 Glucose Monitoring System	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for hospital bedside glucose monitoring for detecting trends and tracking patterns in glucose	Same
Intended use population	Patients in the surgical intensive care unit (SICU)	Same
General Device Characteristic Differences		
Point of access for sample	Central, multi lumen, or peripheral venous catheter	Central or multi-lumen venous catheter

VI Standards/Guidance Documents Referenced:

Not applicable.

VII Performance Characteristics (if/when applicable):

The device in this submission is different from the predicate device in that it is intended for use in the peripherally inserted central catheters described in Table 1 under section VII.F, below. There are no changes to the physical device, and aside from claimed use with the catheters described below the device claims are unchanged from those of the predicate device. Clinical and nonclinical data as reviewed in the clearance of the predicate device, k162042, also support the clearance of this device. For more information regarding the information supporting the performance of this device, see the decision summary for clearance of k162042.

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in k162042.

2. Linearity:

   Previously established in k162042.

3. Analytical Specificity/Interference:

   Previously established in k162042.

   The sponsor has included the following in the labeling:

   - Not all substances which could potentially interfere with OptiScanner® measurement accuracy have been identified. Following the instructions regarding the daily reference check is imperative to screen for potential offsets. The OptiScanner® should not be used during the first 12 hours following the administration of a D-Xylose absorption test.
   - Do not use the OptiScanner® in patients who are being treated with Sodium Thiosulfate.
   - Do not use the OptiScanner® when glycerol is being infused intravenously for the treatment of brain edema.
   - Substances containing maltose, or substances that can be metabolized into maltose, may generate falsely high blood glucose readings on the OptiScanner®.

   Do not use the OptiScanner® in patients that have are receiving any of these medications.

4. Assay Reportable Range:

   The OptiScanner® 5000 will display results between 40 mg/dL and 400 mg/dL glucose.

The reportable range for this device was established in k162042.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Traceability:
   The clinical study performed to support the predicate device, k162042, used YSI 2300 as the comparator method.

   Stability:
   The disposable cartridges and accessories (plasma separation chamber, OptiScanner Heparin Syringe and Adapter) are packaged together and are provided as sterile. The other components of the system (the instrument, a transportation cart, and a barcode scanner) are provided as non-sterile.

   The one year shelf-life of the disposable cartridges and accessories is stated by the sponsor to be up to one year when stored at 5°C - 35°C (41°F -95°F).

   The sterility and shelf life of the OptiScanner® 5000 were previously reviewed in k162042.

6. Detection Limit:

   See linearity, described above in Section VII.A.2.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Previously established in k162042.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See section VII.C.3 below.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Previously established in k162042.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

F Other Supportive Instrument Performance Characteristics Data:

Mechanical Compatibility:

Selected PICCs were assessed for compatibility with the OptiScanner® 5000 Glucose Monitoring System by conducting bench testing that assessed whether samples could be drawn through the catheter to the instrument according to device specifications. Results from these studies support the use of the following PICCs with the OptiScanner® 5000 System, which are listed in the user manual:

Table 1. PICC compatibility with the OptiScanner® 5000 Glucose Monitoring System

Brand	Model	Length (cm)	French Size
Bard	4134115	65	4
Bard	5A5002057	55	4
Bard	5A5001307	55	5
Bard	5A5000574	55	5
Arrow	CA-05052-HP	50	4
Arrow	CA-05041-HP	50	5
Arrow	PR-45541-HPHNM	55	4.5
Arrow	PR-45552-HPHNM	55	5.5
Arrow	PR-45563-HPHNM	55	6

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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