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

A. 510(k) Number:

k162042

B. Purpose for Submission:

New device

C. Measurand:

Plasma glucose from central venous catheter blood draw

D. Type of Test:

Quantitative, mid-infrared (MIR) spectrophotometric assay

E. Applicant:

OptiScan Biomedical Corporation

F. Proprietary and Established Names:

OptiScanner 5000 Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation	Panel
LZF Pump, Infusion Analytic Sampling	II	21 CFR §880.5725 Infusion Pump	General Hospital (80)
PYV Hospital Continuous Glucose Monitoring System		21 CFR §862.1345 Glucose test system	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. 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.

3. Special conditions for use statement(s):
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. 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 central line occlusions were not studied in the trial, it should be noted that the CVCs 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.

4. Special instrument requirements:

   OptiScanner 5000 Instrument

I. 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   VIA Medical Corp Pump/Blood Chemistry Monitor

2. Predicate 510(k) number(s):

   k951739

3. Comparison with predicate:

   Due to an administrative error, the predicate device indications for use in the similarities table below erroneously stated 'same' and has now been corrected to 'similar'.

Similarities		
Item	Candidate Device: OptiScanner 5000 Glucose Monitoring System	Predicate Device: VIA Medical Corp Pump/Blood Chemistry Monitor (k951739)
Indications for Use	Intended for hospital bedside glucose monitoring for detecting trends and tracking patterns in glucose	Similar

Differences		
Item	Candidate Device: OptiScanner 5000 Glucose Monitoring System	Predicate Device: VIA Medical Corp Pump/Blood Chemistry Monitor (k951739)
Patient use population	Patients in the surgical intensive care unit (SICU)	Hospitalized patient
Test Principle	Spectrophotometric	Enzymatic
Sample Type	Venous blood	Venous or arterial blood
Point of access for sample	Central venous catheter	Peripheral venous and arterial lines
Sampling Frequency	15 minutes	5 minutes

K. Standard/Guidance Document Referenced (if applicable):

IEC 60601-1-2, Medical electrical equipment Part 1. General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic compatibility – Requirements and Tests Electromagnetic Compatibility - Requirements and Tests (2007).

ISO 10993-1 (2009), Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

ISO 11137-1 (2010), Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013)].

ISO 11137-2 (2013), Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

ISO 11607-1 (2006), Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)].

ISO 11607-2 (2006), Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)].

L. Test Principle:

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) or multi-lumen access catheter. 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.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. *Precision/Reproducibility:*

      Due to an administrative error, it was previously unclear that the sponsor evaluated precision in two separate studies and the data presented was only for the second study. Also due to an administrative error, the description for the second study erroneously listed the number of days as 16 and is now corrected.

      The sponsor evaluate precision in two studies. In the first study, the sponsor evaluated repeatability using pooled venous whole blood samples adjusted to five glucose levels (40, 80, 130, 200 and 400 mg/dL). Each glucose level was measured in replicates of ten on each of ten OptiScanner 5000 units using three cartridge lots for a total of 500

tests (5 glucose levels, 10 units, 10 replicates per unit). Each sample was measured on the OptiScanner and the comparator method, Yellow Springs Instrument (YSI).

In a second study, the sponsor evaluated repeatability and intermediate precision using pooled plasma adjusted to five different glucose levels (40, 80, 130, 200 and 400 mg/dL). Each glucose level was run on ten OptiScanner 5000 units, using 5 lots of cartridges, for two runs per day over 20 days.

Results for the second study are summarized in the table below:

	Mean Glucose (mg/dL)	43	81	131	208	397
	N	799	799	800	799	799
Day	SD	1.39	0.81	1.39	4.83	9.50
	CV (%)	3.22	1.00	1.06	2.32	2.39
Run	SD	1.31	3.58	4.14	5.70	7.34
	CV (%)	3.04	4.40	3.16	2.74	1.84
Replicate (Repeatability)	SD	1.73	1.48	1.81	1.31	2.84
	CV (%)	4.01	1.82	1.38	0.63	0.72
Instrument	SD	3.10	4.54	5.25	6.55	15.75
	CV (%)	7.19	5.58	4.01	3.16	3.97
Combined/Total SD		4.03	6.02	7.07	10.02	20.01
Combined/Total CV (%)		9.35	7.41	5.39	4.83	5.04

b. Linearity/assay reportable range:

The concentration range evaluated in the clinical study ranged from 64 mg/dL to 366 mg/dL. The OptiScanner 5000 will display results between 40 mg/dL and 400 mg/dL glucose.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:
The clinical study was performed using the OptiScanner 5000 Glucose Monitoring System and YSI 2300 as the comparator method (see Section M.3.c.).

Stability:
The disposable cartridges and accessories (plasma separation chamber, OptiScanner Heparin Syringe and Adapter) are packaged together and are sterilized to an assurance level (SAL) of 10-6 using gamma irradiation. 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 was validated, using accelerated and real-time testing, to be up to one year when stored at 5°C - 35°C (41°F -95°F) according to the requirements of ISO 11607: *Packaging for Terminally Sterilized Medical Devices*, and ASTM D 4169: *Standard Practice for Performance Testing of Shipping Containers and Systems*.

d. *Detection limit:*

See linearity study in Section M.1.b. above.

e. *Analytical specificity:*

Fifty-two endogenous and exogenous substances were evaluated in a bench study to determine the effect of potentially interfering compounds on device performance. Test samples were prepared by spiking potentially interfering substances into pooled heparinized plasma samples. A control sample without interferent was also prepared for each substance. Three concentrations of each substance and three glucose concentrations (60 mg/dL, 120 mg/dL and 250 mg/dL) were analyzed in replicates of three using three OptiScanner 5000 systems. The difference between the test sample and the control sample was calculated.

Substances that did not interfere at any concentration tested are listed in the table below.

Potential Interfering Substance	**Highest concentration tested with no significant interference (mg/dL)**
Acetaminophen	20
Albumin	4900
Ascorbic Acid	3
Aztreonam	24.2
Bilirubin	25
Calcium Gluconate	102.5
Cholesterol	309
Creatinine	10
Dopamine	20
Ethylene Glycol	20
Galactose	10
Glutathione	3.07
Hemoglobin	20,000
Heparin	5 IU/mL
Iohexol	1.4

Potential Interfering Substance	Highest concentration tested with no significant interference (mg/dL)
Isomalt	0.09
Lactate	125
Lacititol	0.09
L-Dopa	0.5
Magnesium in Magnesium Sulfide	6.02
Maltitol	0.09
Pralidoximelodide	1.3
Sodium Citrate	39.7
Sorbitol	0.09
Tazabactam	3.4
Triglycerides	557
Uric Acid	10
Xylitol	0.09

Substances that exhibited a greater than 5 mg/mL bias, compared to the control sample, at any of the concentrations tested during the initial interference screen underwent additional testing at five lower concentrations. The sponsor defined no significant interference to be ≤20 mg/dL bias compared to YSI.

Due to an administrative error, the paragraph below erroneously stated 'concentrations' instead of 'glucose readings' and is now corrected.

For substances that significantly interfere, the device is designed to not give a reading ('no read') when it detects certain interferents at certain concentrations (see table below). A No Read appears as '---' on the screen. The table below provides the highest concentration tested at which no interference was observed and the concentration at which all glucose readings are No Reads. Tested concentrations between the two reported concentrations in the table below resulted in either a biased measurement or as a No Read. Substances that do not have a reported 'concentration at which all measurements are No Reads' (indicated by a '-' below) resulted in either significant bias or a "No Read" (but did not result in a No Read 100% of the time) for all concentrations evaluated greater than the concentration reported in column 2.

Potential Interfering Substance	Highest concentration tested with no significant interference (mg/dL)	Concentration (mg/dL) at which all measurements are No reads (mg/dL)	Therapeutic Concentration (mg/dL)
Amino Acid, FreAmineIII	0	>525	Not available.
Amino Acid,	15	-	Not available.

Potential Interfering Substance	Highest concentration tested with no significant interference (mg/dL)	Concentration (mg/dL) at which all measurements are No reads (mg/dL)	Therapeutic Concentration (mg/dL)
ProcalAmine			
Dextran	0	>450	Not available.
EDTA	25	>100	Not available.
Ethanol	50	>100	0-400[1]
Gentisic Acid	0	>125	0.2-0.6[2]
Glycerol	0	>106.5	Not available.
Hetastarch	175	>700	Not available.
Ibuprofen	25	-	15-30[2]
Icodextrin	14	>56	Not available.
L-Arginine	150	>450	Not available.
Maltose	0	>160	Not available.
Mannitol	306; interference of >20 mg/dL was observed at 50 mg/dL	-	Not available.
MethylDopa	25	>75	0.1-0.75[2]
Piperacillin, Sodium	19.5	-	0.1-0.5[3]
Salicylate	0	-	10-30[2]
Sodium Chloride	248.3 mEq/dL	-	Not available.
Sodium Thiosulfate	5.5	-	Not available.
Tolazamide	0	-	Not available.
Tolbutamide	25	>50	4.5-10[3]
Voluven	0	>175	Not available.
Xylose	0	>100	Not available.

1. Tietz Textbook of Clinical Chemistry. Chapter 49: Fourth Ediction. Edited by CA Butis, ER Ashwood, DE Bruns. Philadelphia, WB Saunders Company, 2006.
2. Clinical and Laboratory Standards Institute Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition (EP7-A2)
3. Schulz M, Iwersen-Bergmann S, Andresen H, Schmoldt A. Therapeutic and toxic blood concentrations of nearly 1000 drugs and other Xenobiotics. Critical Care 2012, 16(4): 136

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.

See also Section M.2.c. below for a list of medications that were present during the clinical study.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The performance of the OptiScanner in the intended use population is described below in Section M.2.c.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

The performance of the OptiScanner 5000 Glucose Monitoring System in surgical intensive care unit (SICU) patients was established in a non-randomized, observational clinical study conducted on 160 SICU patients. During the study

venous blood was obtained from patients through central venous catheters (CVC). Blood was withdrawn for measurement on the OptiScanner 5000 every 15 minutes and results from the OptiScanner 5000 were compared to results obtained from comparative blood drawn taken 6 to 12 times per day for measurement of the plasma on the Yellow Springs Instruments Model 2300 (YSI 2300; comparator method). A total of 2,804 OptiScanner-comparator method paired samples with a glucose range of 64 to 366 mg/dL were collected during the study. Disposable cartridge use times ranged from 18 to 72 hours during the study.

Glucose results, patient conditions (see Patient Conditions table below for details), and medication information (see the Medications table below for details) were collected during the study. Adverse events that were not determined to be device related were not collected during the study.

The following table provides the analysis of OptiScanner 5000 (OS) values and the percent of data points that fell within 5%, 10%, 15%, 20%, 30%, 40% and >40% of specific glucose ranges on the YSI comparator method (CM).

Agreement (%) of OS-CM paired points stratified by different CM glucose ranges

CM glucose ranges (mg/dL)	Number of paired OS- CM	Percent of OS within 5% of CM	Percent of OS within 10% of CM	Percent of OS within 15% of CM	Percent of OS within 20% of CM	Percent of OS within 30% of CM	Percent of OS within 40% of CM	Percent of OS greater than 40% of CM
Overall	2,804	46.9	75.5	91.1	96.8	99.6	99.9	0.1
<40	-	-	-	-	-	-	-	-
≥40-60	-	-	-	-	-	-	-	-
>61-80	23	17.4	47.8	78.3	87.0	95.7	95.7	4.3
>80-180	2,427	46.2	75.2	90.6	96.7	99.7	100	0.0
>180-300	352	53.4	79.3	95.7	97.7	99.7	100	-
>300	2	50	100	100	100	100	100	-

The following tables show the percentage of concurring OS readings compared to CM values. With ideal performance the OS readings would match the CM values. For example, with perfect concurrence, the shaded boxes would be 100 percent.

Concurrence of CM values and the OS readings using the glucose ranges obtained on the CM.

OS (mg/dL)	CM (mg/dL)									N (Number of OS - CM pair
	<40	40-61	61-80	81-120	121-160	161-200	201-250	251-300	>300	

										readings)
<40	0	0	0	0	0	0	0	0	0	0
41-60	0	0	0	100%	0	0	0	0	0	2
61-80	0	0	24.3%	74.3%	1.4%	0	0	0	0	70
81-120	0	0	0.6%	78.1%	21.3%	0	0	0	0	943
121-160	0	0	0	12.6%	79.3%	8.1%	0.1%	0	0	1128
161-200	0	0	0	0	27.3%	65.7%	6.9%	0	0	458
201-250	0	0	0	0	0	32.3%	60.5%	7.2%	0	167
251-300	0	0	0	0	0	0	20%	77.1%	12.9%	35
>300	0	0	0	0	0	0	0	0	100%	1

Patient Conditions:

The study participants were diagnosed with the following medical conditions at admittance:

Abdominal Aortic	CAD Mitral Stenosis	GI Bleed	Mitral Valve Replacement	Ruptured Abdominal Aortic Aneurysm
Aneurysm	CAD s/p CABG (Coronary Artery Bypass Grafting)	Gunshot Wound	Multiple Trauma	S/p Right Hepatectomy Secondary to Hepatocellular Cancer
Abdominal Pain	Cardiogenic Shock	Heart Failure	MVA Trauma (Motor Vehicle Accident)	SDH (Succinate Dehydrogenase)
Abdominal Wall	Chest pain	Hepatic Mass Resection	Mx Pelvic Fracture	Sepsis
Reconstruction	Chest pain, Unstable Angina	Hyperparathyroidism s/p Parathyroidectomy	Myectomy	Septal Myectomy
Abscess of Neck	Chest Wound	Hypertrophic Cardiomyopathy	Myocardial Infarction	Septic Shock
Accidental Removal of J-Tube	Colon Cancer, Colectomy	Hypotension	Necrotizing Fasciitis	Severe Mitral Regurgitation
Acute Kidney Injury	Colonic Mass Obstruction	Hypotension, Sepsis	Neurogenic Shock due to Traumatic Injury	Small Bowel Obstruction
Acute Myocardial	Colovesical Fistula,	Ileus	NSTEMI, Non-St Segment	Spine Disorder

Infarction	Postoperative		Elevation Myocardial Infarction	
Acute Respiratory Failure	Complex Hip Fracture s/p MCC	Intra-abdominal Sepsis	Orthotopic Liver Transplant with Kidney Transplant	Splenic Infarct
Alcoholic Cirrhosis	Coronary Artery Disease	Intracranial Hemorrhage	Ovarian Cancer	Stab Wound
Anastomotic Leak	Critical Left Leg Ischemia	Laceration of Brachial Artery	Pancreatic Cancer	Abdominal Hysterectomy and Ventral Hernia Repair
Aortic Dissection Repair	Decompensation of Cirrhosis of Liver, Post Liver Transplant	Leaky Mitral Valve	Pancreatitis	Cardiac and Respiratory Arrest
Aortic Stenosis	Dilated Ascending Aorta	Left Arm Cellulitis	Parastomal Hernia Repair	Revascularization of Left Lower Extremity
Aortic Stenosis, AVR	Diverticulitis of Colon	Left Femoral Artery Pseudoaneurysm	Perforated Diverticulitis	Splenectomy for Infarction hematoma
Aortic Valve Narrowing	End Stage Renal Disease	Left Knee Antibiotic spacer infection	Perforated Diverticulitis s/p Resection	Subclavian TAVR
Aortic Valve Replacement	Enterocutaneous Fistula	Left Ventricular Assist Device Insertion (LVAD)	Pneumonia	Succinate Dehydrogenase, tumor
Ascites, Severe Anemia	Esophageal Perforation	Liver Disease	Post Op TAH, BSO, Appendectomy	Superior Mesenteric Artery Thrombosis
Bowel Obstruction	Exploratory Laparotomy	Liver Transplant	Pseudomyxoma Peritoneal, HIPEC	Thoracabdominal Aneurysm
Bowel Perforation	Exploratory Laparotomy Tumor Debulk	Malignant Neoplasm of Pelvis	R common femoral artery occlusion s/p thombectomy	Transapical TAVR
Burn Injury	Fall	Mitral Stenosis and	Redo TVR with	Tricuspid Valve

		Regurgitation	Pulmonary Embolectomy	Repair
CABG (Coronary Artery Bypass Grafting)	Fournier's Gangrene	Mitral Valve Disease	Respiratory Failure	Unstable Angina (Heart disease)
CABG (Coronary Artery Bypass Grafting) w/ AVR (Aortic Valve Replacement)	Gastrointestinal Bleed	Mitral Valve Regurgitation	Respiratory Failure, COPD	Ventral Hernia Repair
CABG, MAZE, Myectomy	Gastrointestinal Discontinuity	Mitral Valve Repair	Retroperitoneal Bleed	Ventricular Septal Myectomy

Medications:
Study participants received the following medications in the SICU during the clinical study:

Acetaminophen	Dextrose	Levofloxacin	Plasma-lyte
Acetaminophen with Codeine #3 (Tylenol with Codeine #3	Diazepam	Levothyroxine	Polyethylene Glycol
Acetazolamide	Diclofenac	Lidocaine	Potassium Chloride
Acetazolamide (Diamox)	Digoxin	Linezolid	Potassium Phosphate; Potassium Sodium
Acetylcysteine 20%	Dilaudid	Lisinopril	Pravastatin
Acyclovir	Diltiazem	Lorazepam	Prednisolone
Adenosine	Diphenhydramine	Losartan	Prednisone
Albumin	Diphtheria/Pertussis, Acel/Tetanus adult	Lovenox	Pregabalin
Albuterol	Dobutamine	Maalox	Preparation-H Rectal ointment
Alprazolam	Docusate	Magnesium Hydroxide	Prismasate Prismasate Bag
Alteplase	Dolutegravir	Magnesium SO4	Procainamide
Amantadine	Donepezil	Mannitol	Prochlorperazine
Amicar	Dopamine	Marcaine	Propofol

Amiodarone	Dorzolamide	Melatonin	Propranolol
Amlodipine	Doxazosin Mesylate	Meperidine	Protamine
Amoxicillin	Duloxetine DR	Meropenem	Protonix
Ampicillin	Emollients	Mesalamine ER	Psyllium
Anti-inhibitor coagulant	Emtricitabine; Emtricitabine / Tenofovir	Methadone	Pyridostigmine
Aquaphor Healing Ointment	Enoxaparin	Methylene blue	Pyridoxine
Artificial Tears	Entecavir	Methylprednisolone	Quetiapine; Quetiapine Fumarate
Ascorbic Acid	Ephedrine	Metoclopramide	Ramelteon
Aspirin	Epinephrine	Metolazone (Zaroxolyn)	Ranitidine
Atenolol	Epoetin alfa	Metoprolol	Recombinant Factor VII
Atorvastatin	Epoprostenol	Metronidazole	Remifentanil
Atracurium	Eptifibatide	Mexiletine	Rifaximin
Atropine	Ergocalciferol liquid	Micafungin	Rocuronium
Atrovent nebulizer	Ertapenem	Miconazole 2%	Ropivacaine
Azathioprine	Erythromycin	Midazolam	Rosuvastatin; Rosuvastatin Calcium
Azithromycin	Escitalopram	Midodrine	Saline Flush
Bacitracin	Esmolol	Milk of Magnesia	Saliva Substitute
Baclofen	Esomeprazole	Milrinone	Sarna Lotion
Basiliximab	Etomidate	Mineral Oil	Scopolamine
Beclomethasone	Famotidine	Mirtazapine (Remeron)	Senna
Benadryl	Fat Emulsion	Montelukast	Sertraline
Bisacodyl	Fenofibrate	Morphine	Sildenafil Citrate
Brimonidine	Fentanyl	Multivitamin	Simvastatin
Brinzolamide	Ferrous Sulfate	Mupirocin	Sodium Bicarbonate
Budesonide	Fibrin sealant component	Mycophenolate	Sodium Chloride
Bumetanide	Finasteride	Mycophenolate Mofetil	Sodium Phosphate; Sodium Phosphate/ Potassium

			Phosphate
Bupivacaine	Flecainide	Mycophenolic Acid	Spironolactone
Bupropion	Fluconazole	NaCHO3	Sterile Water
Calcium Calcium Carbonate; Calcium Carbonate/Vit D	Fludrocortisone	NaCl	Succinylcholine
Calcium Chloride	Flumazenil	NaHCO3 8.4%	Sucralfate
Calcium Citrate	Fluoxetine	Naropin 0.2%	Sufentanil
Calcium Gluconate	Folic Acid	Neomycin Polymyxin B	Sulfamethoxazole; Sulfamethoxazole/ Trimethoprim
Captopril	Fosphenytoin	Neostigmine	Tacrolimus
Carbidopa/Levodopa	Furosemide	Nephrocap	Tamsulosin
Carisoprodol	Furosemide	Nicardipine	Tetanus and Diphtheria Toxoid Vaccine
Carvedilol	Gabapentin	Nicotine	Theophylline tablet
Cefazolin	Gelatin absorbable	Nimodipine	Thiamine (Vitamin B-1)
Cefepime	Gentamicin	Nitroglycerin	Timolol
Cefoxitin	Glycopyrrolate	Nitroprusside	Tiotropium
Ceftaroline Fosamil (Teflaro)	Guaifenesin	Norepinephrine	Tizanidine
Ceftriaxone	Haloperidol	Normal Saline	Torsemide
Celecoxib	Heparin; Heparin Sodium	Nortriptyline	Total Parenteral Nutrition
Cell Saver	Hepatitis B Immunoglobulin	Normal Saline(NS) ½ NS	Tramadol
Cetirizine	Hydralazine	Nystatin	Tranexamic Acid
Chloraseptic	Hydrocodone-acetaminophen	Ocular lubricant	Trazodone
Chlorhexidine	Hydrocortisone	Ofloxacin	Triamcinolone Acet
Chlorothiazide	Hydromorphone	Olanzapine	Trimethoprim/Sulfa
Cholecalciferol	Ibuprofen	Omeprazole	Valganciclovir
Cilostazol	Imipenem-Cilastatin	Ondansetron	Valium
Ciprofloxacin	Human Insulin	Oseltamivir	Vancomycin
Cisatracurium	Insulin Lispro Insulin Detemir Insulin Glargine Insulin (Humulin R)	Oxacillin	Vasolex

	Insulin Regular		
Citalopram	Iodixanol	Oxybutynin	Vasopressin
Clindamycin	Ipratropium Ipratropium/ Albuterol	Oxycodone	Vecuronium
Clonazepam	Iron Sucrose	Oxymetazoline	Vein Graft solution
Clonidine	Isoproterenol	Pancuronium	Venelex
Clopidogrel	Isosorbide Dinitrate	Pantoprazole	Versed
Colchicine	KCL	Papaverine	Vitamin K
Cosyntropin	Ketamine infusion	Paroxetine	Voriconazole
Cyanocobalamin (Vitamin B12)	Ketorolac	Pazopanib HCl (Votrient)	Warfarin
5% dextrose (D5)/ ½ normal saline (NS);	Labetalol	Pepcid	White Petrolatum/ Mineral Oil
D5/Lactate ringers (LR); D5 NS; D5W	Lactated Ringer	Peridex	Zantac
D5LR with 150 gm/L Dextrose	Lactulose	Phenylephrine	Zinc Sulfate
D5W with 150 mEq Sodium Bicarbonate	Lansoprazole	Phenytoin	Ziprasidone
Daptomycin (Cubicin)	Lasix	Phytonadione	Zofran
Desmopressin	Latanoprost	Piperacillin	Zolpidem
Dexamethasone Dexmedetomidine	Levetiracetam		

Alarm Performance

Alarm performance was evaluated to calculate true alarm rates (sensitivity), false alarm rates, missed alarm rates and specificity. The descriptions of each assessment and the results for the alarm rate performance are in the tables below and have been included in the device labeling:

Performance Metric	Definition
True Alarms (Sensitivity)	The OptiScanner 5000 alarmed when it should have. This metric gives users confidence that the OptiScanner 5000 will alarm for hypoglycemia or hyperglycemia when it should.
False Alarms	The OptiScanner 5000 alarmed when it should not have. This metric gives users an understanding of how frequently the OptiScanner 5000 will alarm for hypoglycemia or hyperglycemia when it should not be alarming.

Missed Alarms	The OptiScanner 5000 should have alarmed but did not. This metric gives users an understanding of how frequently the OptiScanner 5000 should have alarmed for hypoglycemia or hyperglycemia but did not alarm.
Specificity	The OptiScanner 5000 did not alarm when it should not have alarmed. This metric gives users an understanding of how frequently the OptiScanner 5000 did not alarm for hypoglycemia or hyperglycemia when it should not have been alarming.

Low Glucose Alarm Performance (±15 Minutes)

	Alarm at 90, Comparator ≤70 mg/dL (hypoglycemia detection)	Alarm at 90, Comparator ≤90 mg/dL
True Alarm Rate (Sensitivity)	100% (3/3)	84% (98/116)
False Alarm Rate	98% (158/161)	42% (72/170)
Missed Alarm	0% (0/3)	16% (18/116)
Specificity	94% (2,643/2,801)	97% (2,616/2,688)

High Glucose Alarm Performance (±15 Minutes)

	Alarm at 150, Comparator ≥180 (hyperglycemia detection)	Alarm at 150, Comparator ≥150
True Alarm Rate (Sensitivity)	99% (357/360)	92% (801/873)
False Alarm Rate	60% (538/895)	14% (135/936)
Missed Alarm	1% (3/360)	8% (72/873)
Specificity	78% (1,906/2,444)	93% (1,796/1,931)

Additional Alarms:
The sponsor includes descriptions of additional alarms in the labeling. These include alarms for saline bag occlusion, air in line to patient, patient line occlusion, and occlusion during blood return.

Human factors study

A human factors-usability analysis was conducted according to EN62366-1:2015, *Medical Devices – Application of Usability Engineering to Medical Devices*.

Usability studies were performed by intended operators of the device to assess tasks determined to be high-risk. Based on the results of the primary summative usability test results, specific design changes were made to the OptiScanner to address usability test findings. A follow-up supplemental usability test was conducted to evaluate the changes to determine the effectiveness in their ability to mitigate the risk associated with the original usability study findings. The usability evaluations performed demonstrated that users understood the instructions provided in the labeling and that they could use the device safely.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Not applicable.

N. Instrument Name:

OptiScanner 5000 Instrument

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X___ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X___.

2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X___ or No _____

3. 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.

4. 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.

5. Calibration:
   The OptiScanner 5000 requires no calibration by the user.

6. Quality Control:
   There is no quality control material for use with the OptiScanner 5000 Glucose Monitoring System.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Hematocrit Study: The effect of different hematocrit levels on the performance of the OptiScanner 5000 was evaluated using donor blood samples with hematocrit levels adjusted to 15, 20, 25, 30, 35, 40, 45, 50, 55 and 60% spiked with glucose to achieve 5 concentrations ranging from 40 to 400 mg/dL (40, 100, 150, 250, 400 mg/dL). Results from the OptiScanner 5000 were compared with results obtained from the comparator, YSI-2300 analyzer. The % biases relative to YSI were acceptable and support the claimed hematocrit range of 15 to 60%.

2. Operating Conditions: The sponsor evaluated temperatures ranging from 20°C to 27°C (68°F – 80.6°F) and relative humidity (RH; non-condensing) ranging from 20% to 60%. OptiScanner 5000 results were compared to results obtained from the YSI-2300 analyzer using donor blood samples. Three temperature and humidity combinations were tested including low temperature/low humidity, average temperature and humidity (23°C/40% RH) humidity, and high temperature/high humidity. No significant effect (relative to YSI) was observed for the temperature and humidity combinations tested. The results support the claimed system operating conditions of a temperature range of 20°C to 27°C and relative humidity range of 32 to 60%.

3. Bubble Sensor: The device is designed to prevent air bubbles from reaching the patient. Two bubble sensors are incorporated into the patient line, which is part of the disposable cartridge, to detect bubbles and generate an alarm when bubbles are detected. Once bubbles are detected, the device stops the pump which prevents blood from being returned to the patient. The sponsor validated this feature and demonstrated that the bubble sensor functions as intended.

4. Biocompatibility
   The sponsor provided acceptable biocompatibility testing on finished and sterilized disposable cartridges that included: cytotoxicity, sensitization, irritation, systemic toxicity (acute), systemic toxicity (sub-acute), pyrogenicity, hemocompatibility, genotoxicity

(reverse mutation assay, chromosomal aberration, in vivo mouse micronucleus), and immunotoxicology tests.

5. Electromagnetic Compatibility and Electrical Safety:
   The sponsor provided appropriate documentation certifying that electromagnetic testing (EMC) has been performed and the OptiScanner 5000 Glucose Monitoring System was found to be compliant. The labeling includes a warning against the use of the OptiScanner 5000 near Magnetic Resonance Imaging (MRI) equipment or Computerized Tomography (CT) equipment.

6. Cleaning and Disinfection:
   The sponsor provided disinfection efficacy testing demonstrating the chosen wipes (Clorox Healthcare Bleach Germicidal Wipes; EPA registration number 67619-12) were effective against Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Klebsialla Pneumoniae, and Mycobacterium terrae when on the exterior surfaces of the device and cart.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

Due to an administrative error, additional conclusions were erroneously included and have now been removed.

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