DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 16, 2017

OPTISCAN BIOMEDICAL CORP.
DON WEBBER
CHIEF OPERATING OFFICER
24590 CLAWITER ROAD
HAYWARD CA 94545

Re: K162042
Trade/Device Name: OptiScanner 5000 Glucose Monitoring System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: II
Product Code: LZF, PYV
Dated: September 15, 2017
Received: September 15, 2017

Dear Don Webber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162042

Device Name
OptiScanner 5000 Glucose Monitoring System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 2. 510(K) SUMMARY

1. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE PREPARED	October 9th, 2017
APPLICANT	OptiScan Biomedical Corp. 24590 Clawiter Road Hayward, CA 94545
OFFICIAL CORRESPONDENT	Don Webber COO, OptiScan Biomedical Corporation phone: (510) 962 -6223 fax: (510) 342-5809 e-mail: dwebber@optiscancorp.com

SECTION 2. 510(K) SUMMARY

510(k) Number	K162042
TRADE NAME	OptiScanner 5000 Glucose Monitoring System
COMMON NAME	Automated, in-line, bedside, glucose monitoring system
MODEL NUMBERS	• OptiScanner Instrument - PN 2004234 • OptiScanner Disposable Cartridge and Accessories - PN 2004756 • OptiScanner Transport Cart - PN 2002168 • OptiScanner Instrument Software and Algorithm - versions 2.12 and 3.0.5.0 respectively
DEVICE CLASSIFICATION	Name: Infusion pump Regulation No: 21 CFR §880.5725 Product Code: LZF – Pump, Infusion Analytic Sampling Class: II Name: Glucose test system Regulation No: 21 CFR §862.1345 Secondary Product Code: PYV – Hospital Continuous Glucose Monitoring System Class: II
PREDICATE DEVICE	VIA Medical Pump/Blood Chemistry Monitor (K951739)

SUBSTANTIALLY EQUIVALENT TO:

The OptiScanner is substantially equivalent in intended use and technological features to the Via Medical GlucoScout (K951739). Both devices are intended to be used to "… monitor blood glucose in an in-hospital setting…"

SUMMARY OF SIMILARITIES / DIFFERENCES:

The OptiScanner acquires samples in an automated fashion at a patient's bedside in the ***same*** way as the predicate device, the GlucoScout. Both devices use a sterile closed system to connect to the patient. Both employ a single-use, single-patient disposable cartridge intended to be used for up to 72 hours of monitoring. In both systems, the blood samples are processed in cartridges. The cartridges in both systems are connected to durable medical equipment (comprised of a hardware and software system) that controls blood sampling, calculates the glucose value, and displays the blood glucose value after each sample. Both systems return the portion of the blood not used for analysis back to the patient with a flushing solution of either saline (OptiScanner, 2.5 mL saline) or calibration solution (GlucoScout, 6 mL calibration solution).

Both systems alarm at clinician determined, preset high and low glucose values, and both systems have patient line alarms.

The biggest difference between the GlucoScout and the OptiScanner is the method used to determine the glucose level from the whole blood sample. The GlucoScout uses an enzymatically-based glucose oxidase method to detect and quantify blood glucose. The OptiScanner, on the other hand, uses a spectrophotometric method to detect and quantify glucose.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OptiScanner® 5000 Glucose Monitoring System ("OptiScanner") is an in-line, automated, bedside, frequent, automated glucose monitoring system that quantitatively measures the concentration of glucose in the blood of patients in a Surgical Intensive Care Unit (SICU). In contrast to Point of Care (POC) glucose measuring devices that measure glucose using enzymatic techniques, the OptiScanner uses a direct, reagent-free, spectrophotometer method to quantify glucose. The system is comprised of the following three (3) primary components:

- OptiScanner **Instrument**
- OptiScanner Transport **Cart**
- OptiScanner Disposable **Cartridge**

The Instrument is the primary hardware component that houses all electrical, mechanical, analytical, and power subsystems. This includes the integrated pump, spectrometer, and the user interface. For mobility and easy access, the Instrument is mounted onto the chassis of a transport Cart. The Cart, in addition to holding the Instrument, holds batteries, IV pole(s) and a bar code scanner. The Cartridge is a disposable, single patient use, sterile component containing the fluid pathway through which the blood is sampled, stored, processed, and analyzed. The Cartridge is the only component of the OptiScanner system that comes in contact with patient blood. Integrated into the cartridge are tubing sets that are used to connect to the patient and to a saline bag. The Cartridge also includes a syringe that is pre-filled with heparin by the user for processing the blood samples. The Cartridge is inserted into the Instruments interface port that provides connections integrating the fluidic components of the Cartridge with the electro-mechanical sub-systems of the Instrument.

INDICATIONS 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.

TECHNICAL CHARACTERISTICS:

To provide frequent, automated glucose monitoring, the OptiScanner samples and measures blood glucose levels every 15 minutes. Small blood samples (~3 mL) are drawn directly from the patient through a vascular access catheter [e.g., Central Venous Catheter (CVC) or Multi-lumen Access Catheter (MAC)]. Only 0.17 mL of the blood sample is retained for analysis and

glucose measurement, with the remaining blood returned to the patient propelled by a volume-controlled saline flush through the catheter. The retained sample is heparinized (with no heparin returned to the patient) to prevent clotting while its processed, and is centrifuged to separate the red blood cells from the plasma. The plasma is then evaluated by the spectrometer to determine the glucose concentration of the blood sample. The system detects glucose by analyzing mid-infrared (MIR) light (7µm - 10µm wavelength) absorption spectra. The use of the MIR region was selected because the primary spectral peaks for glucose are in this region. After obtaining the absorption spectrum for a specific sample, the system calculates blood glucose levels using a set of Partial Least Squares (PLS) regression algorithm. For safety, if the system encounters an unknown interfering substance, it stores the spectral information, and may not provide a glucose measurement value. Blood glucose results are continuously displayed and plotted on a graphical user interface (touchscreen) for ease of monitoring by users (healthcare providers).

This quantitative method provides a robust, stable, and reproducible analytical method for glucose measurement. Because the sample analysis is based on the physical absorption properties of the glucose, readings from the OptiScanner are not subject to drift as they are with chemically-based systems.

PERFORMANCE STANDARDS:

No performance standards have been established by the Agency to date that apply to this device.

SUMMARY OF NONCLINICAL TESTING:

Comprehensive design verification and validation testing was performed on the OptiScanner 5000. Testing provided objective evidence that the OptiScanner 5000 is safe and effective for its intended use of automated glucose monitoring of patients in the Surgical Intensive Care Unit. Results from extensive bench testing demonstrated the function, performance, and safety of the device to meet its intended use. Bench testing included sub-system design verification testing, system function and performance testing, safety feature testing, and blood glucose measurement validation. In addition, *in vivo* safety testing in a large animal model demonstrated that the device can safely and reliably draw, analyze, and return blood to a patient.

Electrical safety and electromagnetic compatibility (EMC/EMI) testing was performed to verify that the device is in compliance with harmonized safety standards for medical electrical equipment (IEC 60601-1 and 60101-1-2). Biocompatibility testing confirmed that the materials of construction for the device in contact with patient blood are biocompatible and safe for its intended patient contact. Sterilization and packaging validation of the OptiScanner 5000 Disposable Cartridge confirmed the device is provided to the user sterile (SAL 10^{-6}) and that package integrity is maintained for the duration of its shelf-life. Software verification/validation testing established the software for the device was thoroughly verified to meet its defined requirements and documented in accordance with FDA guidance documents. Summative usability testing established the system design met usability requirements and addressed potential use errors through inherent design or safety features. Overall, testing confirmed that the OptiScanner 5000 can be used according to its intended use and in an equivalent manner to the predicate device.

SECTION 2. 510(K) SUMMARY

SUMMARY OF CLINICAL TESTING:

The **M**anual vs. **A**utomated Mo**N**itoring **A**ccuracy of **G**lucos**E** IDE Study (MANAGE IDE) was a prospective, multi-center, non-randomized, observational study, with matched samples, comparing the blood glucose levels reported by the OptiScanner® 5000 Glucose Monitoring System (OptiScanner) with a standard blood glucose reference control device, (Yellow Springs Instruments 2300, [YSI]). Data were obtained from 160 Surgical Intensive Care Unit subjects with 2,804 matched OptiScanner-YSI pairs. There were no device-related adverse events and no unexpected device effects that occurred during the clinical study. There were two non-device related serious adverse events during the course of the trial. The OptiScanner also met both the primary and secondary endpoints for accuracy and precision. When compared to the gold standard YSI readings, the overall MARD for the OptiScanner was 7.28%. With an upper one-sided 97.5% confidence and accounting for variance due to subject and random error, MARD was 7.50%. The overall population CV was 10.31% with an upper one-sided 97.5% confidence limit.

SUBSTANTIAL EQUIVALENCE DISCUSSION:

Automated, in-line, bedside glucose monitoring has been commercially available in the US for 20 years (GlucoScout, K951739). The GlucoScout and the OptiScanner are both intended to be used in an in-hospital, point of care (POC) setting to monitor blood glucose at a patient's bedside in an automated fashion at preset time intervals. Both devices monitor only one patient at a time. A technological comparison suggests that the key features of the OptiScanner 5000 are the same as those for the GlucoScout. The OptiScanner acquires samples in an automated fashion at a patient's bedside in the ***same*** way as the GlucoScout. Both devices use a sterile closed system to connect to the patient. Both employ a single-use, single-patient disposable cartridge intended to be used for up to 72 hours of monitoring. In both systems, blood samples are processed in the cartridge. The cartridges in both systems are connected to durable medical equipment (a hardware and software system) that controls blood sampling, calculates the glucose value, and displays the blood glucose level after each sample. Both systems return the portion of the blood not used for analysis back to the patient with a flushing solution of either saline (OptiScanner) or calibration solution (GlucoScout). Both systems alarm at clinician determined, preset high and low glucose values, and both systems have patient line alarms. The extensive suite of bench, electrical, mechanical, biocompatibility, sterilization, software, animal and usability testing confirm that the OptiScanner can be used in an equivalent manner to the GlucoScout, namely, to automatically monitor blood glucose at patient bedside.

Bench, electrical, mechanical, biocompatibility, sterilization, software, animal, clinical and usability testing confirm that the OptiScanner has met all of its predetermined performance criteria without raising any new or untoward performance issues.

Based on the above, OptiScan believes that the substantial equivalence of the OptiScanner to the GlucoScout has been demonstrated, and that there is both a regulatory and scientific basis for market clearance.

SECTION 2. 510(K) SUMMARY

Comparison of Proposed Device to the Predicate

DEVICE FEATURE	OPTISCANNER 5000 GLUCOSE MONITORING SYSTEM	VIA MEDICAL GLUCOSCOUT
Indications for Use	"…an automated, bedside, glucose monitoring system designed for in-hospital use in patients in the surgical intensive care unit"	"…bedside monitoring of blood glucose levels in whole blood on a real-time basis by accessing an intravenous or arterial site"
Target Patient population	Patients in the surgical intensive care unit	Not specified
Key Indication Modifying Statement(s)	"…not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia"	None
Point of Care	In-Hospital	In-Hospital
Glucose quantification method	Spectrophotometric detection of glucose	Electrochemical biosensor, amperometric (glucose oxidase)
Single use Disposables?	Yes. Sampling cartridge	Yes. Sampling cartridge
Duration of single use for disposables	72 hours	72 hours
Source of sample	Venous blood	Venous or arterial blood
Point of access for sample	Central venous catheter (CVC) or multi-lumen access catheter (MAC)	Venous and arterial lines
Invasive / indwelling components?	No. Connects to central venous catheter (CVC) or multi-lumen access catheter (MAC) line	No. Connects to venous or arterial access lines
Sample acquisition method	Blood draw (3 mL) through connection to venous access. 0.17 mL retained, heparinized and analyzed. Rest of blood returned to patient with 2.5 mL saline flush.	Pump reverses and draws sample through venous/arterial access into sensor set. After analysis, sample is returned to patient along with 6 mL calibration solution.
Sample size required for analysis	0.17 mL	0.5 mL - 1.2 mL
Average fluid infused into patient / hr (excluding blood return) during monitoring	10 mL saline (assumes measurement every 15 minutes)	77 mL saline + calibration solutions (assumes measurement every 5 minutes + 5 mL saline KVO)
Sampling frequency	15 minutes	5 minutes
Measuring range	40 - 400 mg/dL	30 - 600 mg/dL
Hematocrit range	15% - 60%	Unknown
Requires use of heparin	Yes, but discarded with portion of blood sample that is analyzed (0.17 mL). Heparin is not infused into patient.	Yes, heparin is infused into patient in sample flush.
Physician determined high and low glucose values?	Yes	Yes
Alarms		
High / Low Glucose	Yes	Yes
Air in line / Occlusion	Yes	Yes
Calibration	At factory. None required under normal use.	Self-calibrating between readings.

SECTION 2. 510(K) SUMMARY

DEVICE FEATURE	OPTISCANNER	VIA MEDICAL GLUCOSCOUT
System Accuracy	MARD 7.28% Based on pivotal trial results with 160 SICU patients (2,804 matched OptiScanner / YSI pairs).	± 10% based bench testing using standards and on a study in diabetic subjects admitted to the metabolic ward (n=7).
Temperature sensitive	No	Yes
Data storage	Yes, 72 hours of data	Yes, 12 hours of data
Back-up battery power?	Yes, 3 hours of operation w/o AC power	Yes, 3 hours of operation w/o AC power
Single patient use disposables	Yes	Yes