February 5, 2020

Optiscan Biomedical Corporation
Charles Zimliki
Vice President of Regulatory, Quality, and Clinical Affairs
24590 Clawiter Road
Hayward, California 94545

Re: K192785
Trade/Device Name: OptiScanner® 5000 Glucose Monitoring System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZF, PYV
Dated: January 2, 2020
Received: January 2, 2020

Dear Charles Zimliki:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k192785

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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This K192785 510(k) Summary was prepared in accordance with 21 CFR 807.92.

1. Submitter

Applicant:	OptiScan Biomedical Corporation 24590 Clawiter Road Hayward, CA 94545
Official Correspondent:	Charles Zimliki Vice President of Regulatory, Quality, and Clinical Affairs Phone: (240) 350-6690 Email: czimliki@optiscancorp.com
Date Prepared:	31 January 2020

2. Device Information

Trade Name:	OptiScanner® 5000 Glucose Monitoring System
510(k) Number:	K192785
Common Name:	Automated, in-line, bedside, glucose monitoring system
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 Product Code: PYV – Hospital Continuous Glucose Monitoring System Class: II

3. Predicate Device Information

Trade Name:	OptiScanner® 5000 Glucose Monitoring System (K162042)
510(k) Number:	K162042
Common Name:	Automated, in-line, bedside, glucose monitoring system
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 Product Code: PYV – Hospital Continuous Glucose Monitoring System Class: II

4. Device Description

The main features of the OptiScanner® 5000 Glucose Monitoring System are described below. There have been no changes to the OptiScanner Instrument, Cart, or Cartridge. They are identical to those cleared in K162042.

The OptiScanner® 5000 Glucose Monitoring System ("OptiScanner") is an automated, bedside glucose monitoring device that quantitatively measures the concentration of glucose in the blood of patients in the 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 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 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 contacts 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 intended to be 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.

5. 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.

6. Comparison of Technical Characteristics with the Predicate Device

There are no differences in the technological characteristics between the proposed device and the predicate device (K162042). The purpose of this Traditional 510(k) is to seek an update to the device labeling (User Manual) to:

1) Update the listing of central venous catheters in “IV Catheters” section that can be used with the OptiScanner 5000 when performing the patient blood draw
2) Add clarification to “Catheter Placement” section regarding the description of the “proximal port” of the central venous catheter

The physical device remains unchanged from the predicate (K162042), with the only change being a revision to the device labeling. Table 1 provides a technological comparison between the proposed device and the predicate device.

Table 1: Comparison of Subject Device to Predicate

Device Feature	Subject Device OptiScanner 5000	Predicate Device OptiScanner 5000 (K162042)	Comments
User Manual (OptiScanner Instrument)	The OptiScanner® 5000 User's Manual	The OptiScanner® 5000 User's Manual	**MODIFIED** Subject of this 510(k) filing: Chapter 2: "IV Catheters" (including Figure 41) updated to include additional IV catheters which have been successfully evaluated for compatibility with the OptiScanner system. "Catheter Placement" updated to add clarifying text. No other revisions have been made to the User Manual
Instructions for Use (OptiScanner Disposable Cartridge)	Instructions for Use, OptiScanner® 5000	Instructions for Use, OptiScanner® 5000	Unchanged
Product Labeling (OptiScanner Disposable Cartridge)	• Disposable Cartridge, Tyvek/Box • Disposable Cartridge, Shipper	• Disposable Cartridge, Tyvek/Box • Disposable Cartridge, Shipper	Unchanged

Device Feature	Subject Device OptiScanner 5000	Predicate Device OptiScanner 5000 (K162042)	Comments
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.	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.	Unchanged
Intended Use	The OptiScanner® 5000 Glucose Monitoring System is intended for in-vitro diagnostic use	The OptiScanner® 5000 Glucose Monitoring System is intended for in-vitro diagnostic use	Unchanged
Target patient population	Patients in the surgical intensive care unit	Patients in the surgical intensive care unit	Unchanged
Key indication-modifying statement	"…not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia"	"…not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia"	Unchanged
Point of care	In-hospital	In-hospital	Unchanged
Glucose quantification method	Spectrophotometric detection of glucose	Spectrophotometric detection of glucose	Unchanged
Single use disposables?	Yes (sampling cartridge)	Yes (sampling cartridge)	Unchanged
Duration of single use disposables	72 hours	72 hours	Unchanged

Device Feature	Subject Device OptiScanner 5000	Predicate Device OptiScanner 5000 (K162042)	Comments
Source of sample	Venous blood	Venous blood	Unchanged
Point of access for sample	Central venous catheter (CVC), Peripherally Inserted Central Catheters (PICC) or multi-lumen access catheter (MAC)	Central venous catheter (CVC) or multi-lumen access catheter (MAC)	Added access by Peripherally Inserted Central Catheters (PICC)
Invasive / indwelling components?	No. Connects to central venous catheter (CVC), peripherally inserted central catheters (PICC), or multi-lumen access catheter (MAC) line.	No. Connects to central venous catheter (CVC) or multi-lumen access catheter (MAC) line.	Added Peripherally Inserted Central Catheters (PICC)
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.	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.	Unchanged
Sample size required for analysis	0.17 mL	0.17 mL	Unchanged
Average fluid infused into patient during monitoring (excluding blood return)	10 mL saline / hour (assumes measurement every 15 min)	10 mL saline / hour (assumes measurement every 15 min)	Unchanged
Sampling frequency	15 min	15 min	Unchanged
Measuring range	40 - 400 mg/dL	40 - 400 mg/dL	Unchanged
Hematocrit range	15-60 %	15-60 %	Unchanged
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, but discarded with portion of blood sample that is analyzed (0.17 mL). **Heparin is not infused into patient.**	Unchanged
Physician-determined high and low glucose values?	Yes	Yes	Unchanged
Alarms			

Device Feature	Subject Device OptiScanner 5000	Predicate Device OptiScanner 5000 (K162042)	Comments
High / low glucose	Yes	Yes	Unchanged
Air in line / occlusion	Yes	Yes	Unchanged
Calibration	At factory (None required under normal use)	At factory (None required under normal use)	Unchanged
System accuracy	MARD 7.28% Based on pivotal trial results with 160 SICU patients (2,804 matched OptiScanner / YSI pairs).	MARD 7.28% Based on pivotal trial results with 160 SICU patients (2,804 matched OptiScanner / YSI pairs).	Unchanged
Temperature sensitive	No	No	Unchanged
Data storage	Yes (72 hours of data)	Yes (72 hours of data)	Unchanged
Back-up battery power	Yes (3 hours of operation w/o AC power)	Yes (3 hours of operation w/o AC power)	Unchanged
Single patient use disposables	Yes	Yes	Unchanged

7. Performance Standards

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

8. Summary of Non-Clinical Testing

A comprehensive bench testing program was originally executed as reported in K162042 for the OptiScanner 5000 System to verify the function, performance, and safety of the device. This Traditional 510(k) seeks FDA clearance of revisions the product labeling (User Manual) to include Peripherally Inserted Central Catheters (PICC) for which compatibility has been demonstrated, and to add clarifying language to the User Manual regarding optimal placement of the central venous access catheter port. All other elements of the OptiScanner system are unchanged and as a result only a subset of the testing performed in the Original 510(k) filing was repeated to support the proposed change. The compatibility requirements of PICCs were assessed through in vitro design verification tests, evaluating the mechanical compatibility of the PICCs to the OptiScanner patient connector as well as blood draw performance relative to Central Venous Catheters (CVCs). Test results demonstrated that the PICCs evaluated performed adequately for their ability to draw blood within the acceptance criteria limits, and that the evaluated PICCs were mechanically compatible with the patient connector on the disposable cartridge. Overall, the test results demonstrate that PICCs can be used with the OptiScanner system in accordance with its intended use and in an equivalent manor to its use with CVCs.

9. Summary of Clinical Testing

No clinical data were required for this submission.

10. Conclusion

The revised labeling that OptiScan is requesting for the proposed OptiScanner® 5000 Glucose Monitoring System is to update the listing of central catheters to which compatibility with the OptiScanner system has been established. Additionally, the labeling updates provide clarification regarding the description of the “proximal port” of the central catheter. The submitted information demonstrate substantial equivalence to the predicate.