November 24, 2020

Opsens Inc.
Marc Chaunet
Director, Regulatory Affairs and Quality System
750 boulevard Du Parc Technologique
Quebec, QC G1P 4S3
Canada

Re: K202943
Trade/Device Name: OptoMonitor 3
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO
Dated: September 24, 2020
Received: September 30, 2020

Dear Marc Chaunet:

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); 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,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics, & Monitoring Devices
Office of Cardiovascular Devices
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)*
K202943

Device Name
OptoMonitor 3

Indications for Use *(Describe)*
To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/ or any interventional procedures.

Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel desease.

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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5 510(K) SUMMARY OPTOMONITOR 3

1. SUBMITTER

Address: Opsens, Inc.

750, Boulevard du Parc Technologique

Quebec (Quebec) G1P 4S3

Phone: 418.781.0333 ext.: 3408

Fax Number: 418-781-0024

Contact Person: Marc Chaunet, Regulatory Affairs and Quality System Director

Email: marc.chaunet@opsens.com

Date Prepared: November 20, 2020

2. DEVICE

Name of Device: OptoMonitor 3

Common or Usual Name: Pressure Monitor

Classification name: Transducer, pressure, catheter tip (870.2870)

Regulatory Class: II

Product Code: DXO

3. PREDICATE DEVICE

OptoMonitor 3 System cleared via K193620 (cleared on 06/18/2020). This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The proposed OptoMonitor 3 and its components are considered accessories to Opsens OptoWire™ pressure guidewires and are intended for use with legally marketed pressure guidewires.

The proposed OptoMonitor 3 includes an Optical Unit (OU), a Display Unit (DU), a Handle Unit (HU) and accessories (cables, power supply, etc).

The device is a non-sterile, non-patient contact device.

5. INDICATIONS FOR USE

The OptoMonitor 3, in conjunction with the OptoWire™ pressure guidewire, is indicated for use to measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or other any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed OptoMonitor 3 is substantially equivalent to the OptoMonitor 3 cleared via K193620 on 06/18/2020.

Indications for Use for the OptoMonitor 3 remains unchanged from the cleared Indications for Use of the OptoMonitor 3 K193620 on 06/18/2020.

The technological characteristics of the proposed OptoMonitor 3 are essentially the same as for the OptoMonitor 3 cleared via K193620 on 06/18/2020. The main difference between the subject device and its predecessor resides in the following:

OPTICAL UNIT

- Bluetooth communication between the Optical and Display units (cabled ethernet / serial offered as backup)

DISPLAY UNIT

- Bluetooth communication between the Optical and Display units (cabled ethernet / serial offered as backup)
- A new 10 inch DU option

SOFTWARE

- DICOM network and terminology were updated for clarity
- Minor changes to user interface including optimization of button positions, dPR manual scale, patient data entry, showing values as the cursor moves, and the option to view previous recordings.

These changes are validated in accordance with Opsens QMS including code review, unit testing, system testing, and regression testing. The changes have been evaluated through the Risk Management Process and no new questions of safety and effectiveness were identified. Existing questions of safety and effectiveness are valid for the proposed device. Any change raises a question concerning whether its performance can be expected to be equivalent with the predicate. Performance testing has confirmed equivalence. No new questions of safety and effectiveness were identified during the execution of Verification and Validation activities. While reviewing the device risk management file, no other security issues were found related to the addition of the wireless function.

Therefore, the proposed device, OptoMonitor 3, meets substantial equivalence requirements with regards to the legally marketed predicate OptoMonitor (K192340 cleared on 12/12/2019).

For detailed comparison, refer to the Substantial Equivalence table on the following pages.

Characteristics	OptoMonitor 3 (K202943)	OptoMonitor 3 (K193620)	Differences
Intended Use	To be used for pressure measurements in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or other any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.	To be used for pressure measurements in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or other any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.	Same
General Indication for use	The OptoMonitor 3 is a diagnostic computer intended for use in catheterization and related cardiovascular specialty laboratories to compute and display various physiological parameters based on the output from a measuring device.	The OptoMonitor 3 is a diagnostic computer intended for use in catheterization and related cardiovascular specialty laboratories to compute and display various physiological parameters based on the output from a measuring device.	Same
FFR Capability	Yes	Yes	Same
Basis for FFR Determination	Ratio of whole heartbeats of Pd and Pa	Ratio of whole heartbeats of Pd and Pa	Same
Operating Temperature	15°C to 30°C	15°C to 30°C	Same
Operating Relative Humidity	10% to 85% non-condensing	10% to 85% non-condensing	Same
Operating Pressure	70 to 106 kPa	70 to 106 kPa	Same
Pressure Range	-30 to 300 mmHg	-30 to 300 mmHg	Same
Pressure Accuracy	+/- 1 mmHg plus +/- 1% of reading (pressure range -30 to 50 mmHg) or +/- 3% of reading (pressure range 50 to 300 mmHg)	+/- 1 mmHg plus +/- 1% of reading (pressure range -30 to 50 mmHg) or +/- 3% of reading (pressure range 50 to 300 mmHg)	Same
Zero Drift	<1 mmHg/h	<1 mmHg/h	Same
Electrical Isolation	Class 1	Class 1	Same
User Interface	Bedside: Touch screen Control room: Yes	Bedside: Touch screen Control room: None	Same, except for the addition of a control room.
Auto-zeroing	Yes	Yes	Same
Real Time Curves	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure	Same

Characteristics	OptoMonitor 3 (K202943)	OptoMonitor 3 (K193620)	Differences
Real Time Numerical Values	Mean aortic pressure, mean distal pressure, FFR, dPR	Mean aortic pressure, mean distal pressure, FFR, dPR	Same
Minimum Pd/Pa Cursor (Detection of FFR Locus)	Yes	Yes	Same
Recording Values	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd	Same
Display Monitor	LCD	LCD	Same
Display Unit size	15 inch 10 inch	15 inch	Equivalent. Refer to **Section 18** for test data.
Bluetooth	Bluetooth communication between the Optical and Display units (cabled ethernet / serial offered as backup)	Cabled ethernet / serial communication between the Optical and Display units	Equivalent. Refer to **Section 17** for test data.
Aortic Input	Low Level (5µV/V/mmHg)	Low Level (5µV/V/mmHg)	Same
Distal Input	OptoWire (optical)	OptoWire (optical)	Same
AUX Input	High Level (100 mmHg/V)	High Level (100 mmHg/V)	Same
Distal Output	Low Level (5µV/V/mmHg)	Low Level (5µV/V/mmHg)	Same
Pressure Guidewire	Opsens OptoWire™	Opsens OptoWire™	Same

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC) were assessed with respect to the software change and the system was found to comply with Electrical Safety and Electromagnetic Compatibility standards:

- IEC 60601-1:2012 (Consolidated text - edition 3.1) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC60601-1-2:2007 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (third edition)
- IEC60601-1-2:2014 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests (fourth edition)

Wireless coexistence testing of the system was successfully tested per ANSI/IEEE C63.27:2017 in accordance with the FDA guidance (2013) Radio Frequency Wireless Technology in Medical Devices.

No new questions of safety and effectiveness were identified during review of Risk Management documentation or execution of Verification and Validation activities.

Additionally, the following standards were applied during the development and testing of the OptoMonitor 3:

- EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes.
- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
- IEC 62304:2006 Medical device software -- Software life cycle processesIEC60601-2-34 :2011 Medical Electrical Equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment.
- IEC 60601-1-6:2010 + A1 :2013 Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
- IEC 61000-3-2: 2018 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase)
- IEC 61000-3-3:2013 +AMD1:2017 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection
- IEC 61000-4-2:2008 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
- IEC 61000-4-3:2006 +AMD1:2007+AMD2:2010 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- IEC 61000-4-4:2012 Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test
- IEC 61000-4-5:2014 +AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
- IEC 61000-4-6:2013 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
- IEC 61000-4-8:2009 Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test
- IEC 61000-4-11 :2004+ AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
- IEC CISPR 11:2015 +AMD1:2016+AMD2:2019 CSV (Consolidated version) Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
- IPC-A-610D Acceptability of Electronic Assemblies
- ETSI EN 301 489-17 V2.2.1 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
- ETSI EN 300 328 V2.2.1 Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
- FCC 15.247 Systems Using Digital Modulation
- RSS-247Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and License-Exempt Local Area Network (LE-LAN) Devices

No animal studies or clinical investigations are included with this submission.

8. CONCLUSIONS

The results from these tests mentioned above demonstrate that the technological and performance characteristics of the proposed OptoMonitor 3 is comparable to the predicate device and support substantial equivalence of the device that is the subject of this 510(k).

The results of the verification/validation tests and the risk analysis have demonstrated that the additional features incorporated in the OptoMonitor 3 device do not add any new questions of safety and efficacy and is therefore substantially equivalent to the predicate OptoMonitor 3 System (K193620 cleared on 06/18/2020).