February 18, 2021

Beijing Bywave Sensing Medical Technology Co., Ltd.
Lizhe Zhang
General Manager
Room 501, Buildinctg 22, No.12, Juyuan Middle Road,
Mapo Town, Shunyi District
Beijing, Beijing 101399
China

Re: K201720
Trade/Device Name: LiPPS™ Intravascular Pressure Sensing System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DXO
Dated: January 13, 2021
Received: January 21, 2021

Dear Lizhe Zhang:

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 and 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)*
K201720

Device Name
LiPPS™ Intravascular Pressure Sensing System

Indications for Use *(Describe)*
LiPPS™ Intravascular Pressure Sensing System is intended to be used in an environment like cathlab and for use in blood vessels, including coronary and peripheral vessels, to measure intravascular pressure during angiography and/or interventional procedures. Pressure measurements are obtained to provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel diseases.

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 5: 510(K) Summary

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1900 and 21 CFR 807.92.

The assigned 510(K) Number: K201720

5. 510(K) Summary

5.1. Date of Preparation: 22nd, May, 2020

5.2. Sponsor

Beijing Bywave Sensing Medical Technology Co., Ltd.
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Contact Person: Lizhe Zhang
Position: General Manager
Email: zhanglizhe@bws-tech.com

5.3. Subject Device Identification

Subject Device Name: LiPPS™ Intravascular Pressure Sensing System
Common name: Intravascular Pressure Sensing System
Classification Name(s): Catheter Tip Pressure Transducer/ Catheter Guide Wire
Product Code: DXO, DQX
Regulation Number: 21 CFR 870.2870/ 21 CFR 870.1330
Review Panel: Cardiovascular
Classification: II

5.4. Predicate Device

510(k) Number: K142598
Device Name: OptoWire and OptoMonitor System
Manufacturer: Opsens, Inc.
510(k) Number: K111395
Device Name: PrimeWire PRESTIGE® Plus Pressure Guide Wire
Manufacturer: Volcano Corporation

5.5. Indications for use:

LiPPS™ Intravascular Pressure Sensing System is intended to be used in an environment like cathlab and for use in blood vessels, including coronary and peripheral vessels, to measure intravascular pressure during angiography and/or interventional procedures. Pressure measurements are obtained

to provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel diseases.

5.6. Device Description

The subject device LiPPS™ Intravascular Pressure Sensing System contains H2000 LiPPS™ Analyzer and LiPPS™ Wire Pressure Guide Wire.

The LiPPS™ Wire Pressure Guide Wire is used together with the H2000 LiPPS™ Analyzer in order to measure intravascular pressure. The LiPPS™ Wire contains an optical sensor and an optical fiber to induce the blood pressure and transmit signal. The LiPPS™ Wire can be connected to the analyzer through the companied handle (with an optical cable and an optical connector). The LiPPS™ Analyzer is an electronic signal processing and display units which can process signals received from the LiPPS™ Wire to display intravascular blood pressure and fractional flow reserve (FFR) values, and various connection cables. LiPPS™ Wire and companied handle (with an optical cable and an optical connector) are sterile, single-use devices. The LiPPS™ Analyzer and its accessories are reusable.

5.7. Predicate Devices and Subject Device Comparison

Item	Subject Device LiPPS™ Intravascular Pressure Sensing System	Predicate Device 1 OptoWire and OptoMonitor System (K142598 Opsens, Inc.)	Predicate Device 2 PrimeWire PRESTIGE® Plus Pressure Guide Wire (K111395 Volcano Corp.)	Remark
Device Common/Usual Name	LiPPS™ Intravascular Pressure Sensing System	Intravascular Pressure Monitoring System	PrimeWire PRESTIGE® Plus Pressure Guide Wire	/
Device Class	Class II	Class II	Class II	SE
Product Code/ Regulation Number	DXO, DQX 21 CFR 870.2870/ 21 CFR 870.1330	DXO, DQX 21 CFR 870.2870/ 21 CFR 870.1330	DXO, DQX 21 CFR 870.2870/ 21 CFR 870.1330	SE
Classification Name(s)	Catheter Tip Pressure Transducer Catheter Guide Wire	Catheter Tip Pressure Transducer Catheter Guide Wire	Catheter Tip Pressure Transducer Catheter Guide Wire	SE
Indications for use	LiPPS™ Intravascular Pressure Sensing System is intended to be used in an environment like cathlab and for use in blood vessels, including coronary and peripheral vessels, to measure intravascular pressure during angiography and/or interventional procedures. Pressure measurements are obtained to provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel diseases.	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.	The Prime Wire PRESTIGE® Plus Pressure Guide Wire Device is indicated for use 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 for the diagnosis and treatment of blood vessel disease.	No substantial difference
Intended use	to measure intravascular pressure	To measure pressure … during	to measure pressure … during	Though expressed

Item	Subject Device LiPPS™ Intravascular Pressure Sensing System	Predicate Device 1 OptoWire and OptoMonitor System (K142598 Opsens, Inc.)	Predicate Device 2 PrimeWire PRESTIGE® Plus Pressure Guide Wire (K111395 Volcano Corp.)	Remark
	during angiography and/or interventional procedures	diagnostic angiography and/or other any interventional procedures.	diagnostic angiography and/or any interventional procedure	in different wording, the subject device has same intended purpose with predicate devices. SE
System Components	Sterile, disposable guidewire Reusable signal processor / monitor Embedded software Connecting cables	Sterile, disposable guidewire Reusable signal processor / monitor Embedded software Connecting cables	Sterile, disposable guidewire	SE with predicate device K142598. Predicate device K111395 is only a pressure guide wire.
System Capabilities	Measurement of intravascular blood pressure including FFR.	Measurement of intravascular blood pressure including FFR.	Measurement of intravascular blood pressure and flow including FFR (when used with pressure/flow system)	SE
Prescription Use	Rx Only	Rx Only	Rx Only	SE
Pressure Sensing & Signal Transmission Technology	Fiberoptic sensor & fiber bundle embedded in guidewire	Fiberoptic sensor & fiber bundle embedded in guidewire	Hard wired strain gauge embedded in guidewire	No substantial difference
Sterile, Single Use Patient Contact Component?	Yes –LiPPS™ Wire Pressure Guide Wire	Yes – OptoWire	Yes – PrimeWire Prestige Plus	SE

Item	Subject Device LiPPS™ Intravascular Pressure Sensing System	Predicate Device 1 OptoWire and OptoMonitor System (K142598 Opsens, Inc.)	Predicate Device 2 PrimeWire PRESTIGE® Plus Pressure Guide Wire (K111395 Volcano Corp.)	Remark
FFR Capability?	Yes	Yes	Yes	SE
FFR Viewing	Yes	Yes	N/A	SE with predicate device K142598. Predicate device K111395 is only a pressure guide wire.
Basis for FFR Determination	Simultaneous acquisition of 2 pressure values: distal pressure from sensor embedded in LiPPS™ Wire Pressure Guide Wire; aortic pressure from external pressure transducer	Simultaneous acquisition of 2 pressure values: distal pressure from sensor embedded in OptoWire; aortic pressure from external pressure transducer	Simultaneous acquisition of 2 pressure values: distal pressure from sensor embedded in PrimeWire; aortic pressure from external pressure transducer	SE
Pressure range (analyzer)	-30 to 300mmHg	-30 to 300mmHg	N/A	SE with predicate device K142598. Predicate device K111395 is only a pressure guide wire.
Pressure range (guide wire)	-300 to 300mmHg	-300 to 300mmHg	Unknown	SE
Accuracy	±1mmHg plus ±1% of reading (over the range -30 to 50mmHg) or ±1mmHg plus ±3% of reading (over the range 50 to 300 mmHg)	+/- 1 mmHg plus +/- 1% of reading (pressure range -30 to 50 mmHg) or +/- 3% of reading (pressure	Unknown	SE with predicate device K142598.

Item	Subject Device LiPPS™ Intravascular Pressure Sensing System	Predicate Device 1 OptoWire and OptoMonitor System (K142598 Opsens, Inc.)	Predicate Device 2 PrimeWire PRESTIGE® Plus Pressure Guide Wire (K111395 Volcano Corp.)	Remark
		range 50 to 300 mmHg)		
Zero thermal effect	< 0.3 mmHg / °C	< 0.3 mmHg / °C	< 0.3 mmHg / °C	SE
Zero drift	< 1 mmHg / h	< 1 mmHg / h	Unknown	SE with predicate device K142598.
User Interface	Touchscreen, Remote Control, Barcode scanner	Touchscreen	N/A	No substantial difference
Auto-zeroing	Yes	Yes	N/A	SE with predicate device K142598.
Real Time Curves	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure, Pd/Pa trend curve	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure	N/A	No substantial difference
Real Time Numerical Values	Systolic, diastolic and mean blood pressure (aortic and distal), heart rate, and mean Pd/mean Pa	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa	N/A	No substantial difference
Recording values	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa	N/A	SE with predicate device K142598.
Minimum Pd/Pa Cursor (Detection of FFR Locus)	Yes	Yes	N/A	SE with predicate device K142598.
Display Monitor	LCD	LCD	N/A	SE with predicate device K142598.
Aortic Input	Low Level (5μV/V/mmHg)	High Level (100 mmHg/V)	N/A	Different

Item	Subject Device LiPPS™ Intravascular Pressure Sensing System	Predicate Device 1 OptoWire and OptoMonitor System (K142598 Opsens, Inc.)	Predicate Device 2 PrimeWire PRESTIGE® Plus Pressure Guide Wire (K111395 Volcano Corp.)	Remark
Aortic Output	Low Level (5μV/V/mmHg)	No	N/A	Different
Distal input	LiPPS™ Wire Pressure Guide Wire (optical)	OptoWire (optical)	N/A	SE with predicate device K142598.
Distal output	Low Level (5μV/V/mmHg)	Low Level (5μV /V/mmHg)	N/A	SE with predicate device K142598.
Guide wire OD	0.014”	0.014”	0.014”	SE
Guide wire length	180 cm	175 cm	185 cm, 300 cm	Different
Guide wire material	Stainless Steel; Nitinol	Stainless Steel; Nitinol	Stainless Steel; SS	SE with predicate device K142598.
Guidewire Coating	PTFE; Hydrophilic coating	Teflon; Silicone	Teflon; GlyDx Hydrophilic coating	No substantial difference
Guidewire Coating Material	PTFE; Hydrophilic coating	Teflon; Silicone	Teflon; GlyDx Hydrophilic coating	No substantial difference
Guidewire Tip Configuration	Straight, J angled	Straight	Straight, pre-shaped “J”	No substantial difference
Guide wire Coating Length and Location	Hydrophilic coating: 30cm from the tip PTFE Coating:145cm starts from 5cm from the proximal end	Hydrophilic coating: 32cm from the tip PTFE Coating: 145cm from the proximal end	Hydrophilic coating: 27cm from the pressure sensor PTFE Coating:155cm from the proximal end	No substantial difference
Tip Material	Nitinol core wire + Platinum nickel alloy coil	Nitinol core wire + Platinum nickel alloy coil	Nitinol core wire + Platinum nickel alloy coil	No substantial difference
Tip Flexibility	Straight: 5mm: 2.63, 10mm: 0.73, 20mm: 0.35 J angled: 5mm: 2.63, 10mm: 0.73, 20mm: 0.35	Unknown	Straight: 5mm: 2.62, 10mm: 0.72, 20mm: 0.35 pre-shaped “J”: 5mm: 2.63, 10mm: 0.72, 20mm: 0.35	No substantial difference

Item	Subject Device LiPPS™ Intravascular Pressure Sensing System	Predicate Device 1 OptoWire and OptoMonitor System (K142598 Opsens, Inc.)	Predicate Device 2 PrimeWire PRESTIGE® Plus Pressure Guide Wire (K111395 Volcano Corp.)	Remark
Tip Type and Shape	Straight, J angled	Straight	Straight, pre-shaped "J"	SE with predicate device K111395.
Guidewire Tip Length	3.0 cm	3.5 cm	3.0 cm	SE with predicate device K111395.
Radiopaque Tip?	Yes	Yes	Yes	SE
Pressure sensor	Optical	Optical	Electrical	SE with predicate device K142598.
Accessories with guide wire	Torque device Handle (with an optical cable and an optical connector)	Torque device Handle (with an OptoWire cable and FOIC optical connector) Gauge factor connector	Torque device Handle (with an PrimeWire cable)	SE with predicate device K142598.
Packaging Configuration	The guide wire is in a DHPE coil. The coil, guide wire handle (with an optical cable and an optical connector) and torque device are all fixed on a PETG tray. The whole product is sealed within Tyvek cover material and polymer material. The polymer material PE50 film. The cover material is Tyvek® 1059B of DUPONT.	The guide wire is in a coil. The coil, guide wire handle (with with an OptoWire cable and FOIC optical connector), torque device and Gauge factor connector are all fixed on a tray. The whole product is sealed within Tyvek cover material and polymer material.	The guide wire is in a coil. The coil, guide wire handle (with an an PrimeWire cable) and torque device are all fixed on a tray. The whole product is sealed within Tyvek cover material and polymer material.	SE
Sterilization Method	EO Sterilization	EO Sterilization	EO Sterilization	SE
Shelf Life	2 years	2 years	3 years	SE with predicate device K142598.

5.8. Non-Clinical Test Conclusion

Bench test were conducted to verify that the subject device met all design specifications, as was Substantially Equivalent (SE) to the predicate device.

5.8.1. H2000 LiPPS™ Analyzer

The H2000 LiPPS™ Analyzer in subject device is tested per the following standard, to evaluate its performance. The test results demonstrated that the proposed device comply with the standard requirements.

IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

IEC 60601-2-34:2011 Medical Electrical Equipment - Part 2-34: Particular Requirements For The Basic Safety, Including Essential Performance, Of Invasive Blood Pressure Monitoring Equipment

The software embedded in H2000 LiPPS™ Analyzer has been developed, documented and validated in accordance with industry standards (IEC 62304 – Medical device software – Software life cycle processes) and FDA guidance (GUIDANCE FOR THE CONTENT OF PRE-MARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN DEVICES).

5.8.2. LiPPS™ Wire Pressure Guide Wire

The LiPPS™ Wire Pressure Guide Wire in subject device is sterilized to a 10^{-6} SAL using an ethylene oxide process that has been validated in accordance with ISO 11135.

The LiPPS™ Wire Pressure Guide Wire in subject device is tested per the following standard, to evaluate its performance. The test results demonstrated that the proposed device comply with the standard requirements.

ISO 11070:2014 Sterile single-use intravascular introducers, dilators and guidewires

The following items are tested:

#	Subject
1	Dimensions
2	Visual Inspection
3	Tensile Strength and Tip Pull
4	Torque Strength (Turns to Failure)
5	Torqueability
6	Coating Integrity
7	Particulate Evaluation
8	Lubricity
9	Corrosion Resistance

#	Subject
10	Kink Resistance
11	Fracture
12	Flexing
13	Tip flexibility
14	Radiopacity
15	Accuracy
16	Optical contrast of Interferogram
17	Zero drift/ Zero thermal effect/Sensitivity thermal effect
18	Connection / disconnection test

The LiPPS™ Wire Pressure Guide Wire in subject device was assessed against the International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1. Guidance on selection of tests." The LiPPS™ Wire Pressure Guide Wire in subject device would be classified as an External Communicating Device in contact with the Circulating Blood for a Limited Duration (<24 hours). The following test were performed for any patient / user contacting material which underwent the identical sterilization to the proposed EO sterilization method/facility intended for market release:

Part 1: Pressure Guide Wire (LiPPS Wire, in vivo part)

Test	Standard
Cytotoxicity Study using MTT Method	ISO 10993-5
ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10
ISO Intracutaneous Study in Rabbits	ISO 10993-10
ISO Systemic Toxicity Study in Mice	ISO 10993-11
USP Rabbit Pyrogen Study, Material Mediated	ISO 10993-11 USP41 NF 36 <151>
ASTM Hemolysis Study Direct Contact and Indirect Contact	ISO 10993-4 ASTM F756
Partial Thromboplastin Time Study	ASTM F2382
In Vivo Thromboresistance Study in the Dog NAVI Mode	ISO 10993-4 ASTM F2382
Complement Activation	ISO 10993-4
Platelet Leukocyte Count Study	ASTM F2888

Part 2: Pressure Guide Wire (LiPPS Wire, in vitro part)

Test	Standard
Cytotoxicity Study using MTT Method	ISO 10993-5
ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10
ISO Intracutaneous Study in Rabbits	ISO 10993-10

5.9. Substantially Equivalent Conclusion

The subject device, LiPPS™ Intravascular Pressure Sensing System, is determined to be Substantially Equivalent (SE) to the predicate device, in respect of safety and effectiveness.