May 28, 2026

Bioptimal International Pte. Ltd.
Francis Joey Eduave
QARA Manager
14 Kaki Bukit View
Singapore, 415950
Singapore

Re: K252702

Trade/Device Name: Bioptimal Pulmonary Artery Monitoring Catheter (TD2502NF, TD2502NGF, TD2502NDF, TD2502NCF, TD2502NCGF, TD2502NDGF, TD2502NDCF, TD2502NDCGF, TD2502NXCF, TD2502NDXF, TD2502NXCGF, TD2502NDXGF, TD2502NDXCF, TD2502NDXCGF, TD2502-110NF, TD2502-110NGF, TD2502-110NDF, TD2502-110NCF, TD2502-110NDGF, TD2502-110NDCF, TD2502-110NCGF, TD2502-110NDCGF, TD2502-110NXF, TD2502-110NXGF, TD2502-110NDXF, TD2502-110NXCF, TD2502-110NDXGF, TD2502-110NDXCF ,TD2502-110NXCGF, TD2502-110NDXCGF, TD2602NF, TD2602NDF, TD2602NDCF, TD2602NDXCF, TD2602NDXF, TD2602NCF, TD2602NXF, TD2602NXCF, TD2702NF, TD2702NDF, TD2702NDCF, TD2702NDXF, TD2702NDXCF, TD2702NCF, TD2702NXF, TD2702NXCF, TD2603NF, TD2603NDF, TD2603NDCF, TD2603NDXF, TD2603NDXCF, TD2603NCF, TD2603NXF, TD2603NXCF, TD2703NF, TD2703NDF, TD2703NDCF, TD2703NDXF, TD2703NDXCF, TD2703NCF, TD2703NXF, TD2703NXCF)

Regulation Number: 21 CFR 870.1200

Regulation Name: Diagnostic Intravascular Catheter

Regulatory Class: Class II

Product Code: DQO, DYG

Dated: May 1, 2026

Received: May 1, 2026

Dear Francis Joey Eduave:

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 (the 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

available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHEN C. BROWNING -S

LCDR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252702

Please provide the device trade name(s).

Bioptimal Pulmonary Artery Monitoring Catheter (TD2502NF,TD2502NGF, TD2502NDF,TD2502NCF,TD2502NCGF,TD2502NDGF,TD2502NDCF,TD2502NDCGF, TD2502NXCF,TD2502NDXF,TD2502NXCGF,TD2502NDXGF,TD2502NDXCF,TD2502NDXCGF, TD2502-110NF,TD2502-110NGF,TD2502-110NDF,TD2502-110NCF,TD2502-110NDGF, TD2502-110NDCF,TD2502-110NCGF,TD2502-110NDCGF,TD2502-110NXF,TD2502-110NXGF, TD2502-110NDXF,TD2502-110NXCF,TD2502-110NDXGF,TD2502-110NDXCF,TD2502-110NXCGF, TD2502-110NDXCGF,TD2602NF,TD2602NDF,TD2602NDCF,TD2602NDXCF,TD2602NDXF,TD2602NCF, TD2602NXF,TD2602NXCF,TD2702NF,TD2702NDF,TD2702NDCF,TD2702NDXF,TD2702NDXCF, TD2702NCF,TD2702NXF,TD2702NXCF,TD2603NF,TD2603NDF,TD2603NDCF,TD2603NDXF, TD2603NDXCF,TD2603NCF,TD2603NXF,TD2603NXCF,TD2703NF,TD2703NDF,TD2703NDCF, TD2703NDXF,TD2703NDXCF,TD2703NCF,TD2703NXF,TD2703NXCF)

Please provide your Indications for Use below.

Bioptimal Pulmonary Artery Monitoring Catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Secondary indications are for sampling blood and infusing solutions

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Bioptimal International Pte. Ltd.
Applicant Address	14 Kaki Bukit View Singapore 415950 Singapore
Applicant Contact Telephone	+65 6859 2341
Applicant Contact	Mr. Francis Joey Eduave
Applicant Contact Email	ra-bpi@bioptimalg.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Bioptimal Pulmonary Artery Monitoring Catheter (TD2502NF, TD2502NGF, TD2502NDF, TD2502NCF, TD2502NCGF, TD2502NDGF, TD2502NDCF, TD2502NDCGF, TD2502NXCF, TD2502NDXF, TD2502NXCGF, TD2502NDXGF, TD2502NDXCF, TD2502NDXCGF, TD2502-110NF, TD2502-110NGF, TD2502-110NDF, TD2502-110NCF, TD2502-110NDGF, TD2502-110NDCF, TD2502-110NCGF, TD2502-110NDCGF, TD2502-110NXF, TD2502-110NXGF, TD2502-110NDXF, TD2502-110NXCF, TD2502-110NDXGF, TD2502-110NDXCF ,TD2502-110NXCGF, TD2502-110NDXCGF, TD2602NF, TD2602NDF, TD2602NDCF, TD2602NDXCF, TD2602NDXF, TD2602NCF, TD2602NXF, TD2602NXCF, TD2702NF, TD2702NDF, TD2702NDCF, TD2702NDXF, TD2702NDXCF, TD2702NCF, TD2702NXF, TD2702NXCF, TD2603NF, TD2603NDF, TD2603NDCF, TD2603NDXF, TD2603NDXCF, TD2603NCF, TD2603NXF, TD2603NXCF, TD2703NF, TD2703NDF, TD2703NDCF, TD2703NDXF, TD2703NDXCF, TD2703NCF, TD2703NXF, TD2703NXCF)
Common Name	Diagnostic intravascular catheter
Classification Name	Catheter, Intravascular, Diagnostic
Regulation Number	870.1200
Product Code(s)	DQO, DYG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K160084	Swan-Ganz Flow-Directed Monitoring Catheter	DQO

Device Description Summary

21 CFR 807.92(a)(4)

Indications for use:
Bioptimal Pulmonary Artery Monitoring Catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Secondary indications are for sampling blood and infusing solutions.

Intended Users:
Trained clinical practitioners who are well versed in safe techniques, and the possible complications associated with the device.

Device description:
Bioptimal Pulmonary Artery Monitoring Catheters are extruded stiff polyurethane (PU) tubing with a French Size of 5Fr, 6Fr or 7Fr, connected to a hub carrying 2 or 3 lumens with a total length of 90 or 110 cm. Each catheter is marked every 10 centimeters to indicate

distance from the distal tip. Narrow bands represent 10-centimeter markings while wide bands represent 50-centimeter markings. The extension tubings comprise a proximal and distal extension of 5Fr or 7Fr, and an inflation extension of 6Fr.
Pulmonary Artery Monitoring Catheters are available in both 2-lumen and 3-lumen configurations. The 2-lumen configuration consists of a distal lumen and a balloon lumen, while the 3-lumen configuration includes a distal lumen, a balloon lumen, and a proximal lumen. By design, 2-lumen models do not include a proximal lumen and therefore do not have a proximal port (e.g., located 29 cm from the distal tip) for central venous pressure (CVP) monitoring or infusion purposes.
• Distal PA lumen: This lumen terminates at the catheter tip. Its usage is to monitor the pulmonary arterial pressure (PAP) and pulmonary arterial wedge pressure (PAWP), and to sample mixed-venous blood.
• Balloon lumen: This lumen terminates in a latex balloon near the catheter tip. It provides a means for inflating and deflating the balloon to facilitate flow-directed catheter placement and to measure pulmonary arterial wedge pressure (PAWP).
• Proximal (CVP) lumen: This lumen terminates 29 centimeters proximal to the catheter tip. It is used for measuring right atrial or central venous pressure (CVP), and to infuse solutions.
Pulmonary Artery Monitoring Catheter are supplied sterile (through Ethylene oxide sterilization), non-pyrogenic and are for single use only.

List of materials:
Main body tubing:Stiff Polyurethane (PU),Black Ink
Junction hub:Thermoplastic Polyester Elastomer
Extension tubing: Polyvinyl Chloride (PVC)
Female Connector:Polyvinyl Chloride (PVC)
Contamination Shield:Polyethylene (PE)/Silicone Rubber / Polycarbonate (PC)
Balloon Lumen:Natural Latex,Polycarbonate (PC)/Polyethylene (PE)/Silicone Rubber
Inflation Syringe:Polypropylene (PP) Copolymer/Polypropylene (PP) /Rubber
"S" Tip guide:Polypropylene(PP)
SafetyWedge:Acrylonitrile-Butadiene-Styrene (ABS) Terpolymer/Polyvinyl Chloride(PVC)

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Bioptimal Pulmonary Artery Monitoring Catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Secondary indications are for sampling blood and infusing solutions

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both subject and predicate device has the same indications for use: for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring , for sampling blood and infusing solutions.Both the subject and predicate device has the same design, principles of operation, sterilization process.Although there are some minor differences in the raw materials used, the raw materials for the subject device and the predicate device are all common medical materials used in the medical device field. And subject device has undergone thorough bench tests, chemical tests and biocompatibility studies. The results of the experimental study all met the requirements. This fully demonstrates that the materials used in the subject device are safe and effective for clinical use. The subject device available in 5 French, 6 French, 7 French with having 90cm or 110cm, and the predicate device available in 4 French, 5 French, 6 French, 7 French with both having 60cm or 110cm catheter length. The catheter size does not affect the overall function and intended use of the device. Because there are some slight differences in the raw materials used, the subject device was subjected to complete biocompatibility test without omission according to ISO 10993-1:2018 requirements and was chemically profiled for two hundred and twenty-four (224) substances in the candidate list of substances of very high concern (SVHC) as mandated by Regulation (EC) No. 1907/2006 concerning REACH. The results of the complete biocompatibility test regimen showed that Bioptimal Pulmonary Artery Monitoring Catheter is safe and complies with ISO test requirements. While the chemical profiling of Bioptimal Pulmonary Artery Monitoring Catheter using the state-of-the-art semi-quantitative analysis showed that the subject device is safe and has very low concentrations of detected leachable analytes. At these very low levels, toxicological risk arising from the leaching of these harmful substances is very minimal and the risk to patient safety during use of the device is low. Therefore, the raw materials differences of the predicate device with respect to the subject device design and composition does not affect the safety and effectiveness of the subject device (Bioptimal Pulmonary Artery Monitoring Catheter).

Technological Comparison

21 CFR 807.92(a)(6)

Both the subject and predicate device has the same characteristics:
1. Design - models come with balloon, with S-Tip, with double lumen or triple lumen .
2. Some slight differences in the raw materials used. However, the raw materials are all common medical materials used in the medical device field.

4. Principle of Operation - Monitoring catheters are available in both double and triple lumen models. In double lumen catheters, the larger lumen terminates at the distal tip of the catheter and is used to monitor pulmonary artery and wedge pressures; the distal lumen may also be used for sampling of mixed venous blood and infusing solutions. The smaller lumen permits balloon inflation and deflation. Triple lumen monitoring catheters have the same capabilities as double lumen catheters with the additional (proximal) lumen for central venous pressure monitoring. Refer to the Specifications for proximal lumen port location by model.
5. Device dimensions - The subject device is 5 French, 6 French, 7 French with having 90cm or 110cm size while the predicate device is available in 4 French, 5 French, 6 French, 7 French with both having 60cm or 110cm catheter length. The catheter size does not affect the overall function and intended use of the device.
6. Sterilization process - Ethylene Oxide (EO) Sterilization according to ISO 11135:2014 standard

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bioptimal Pulmonary Artery Monitoring Catheter is categorized as externally communicating medical devices in contact with circulating blood no longer than 3 days (prolonged exposure). According to ISO 10993-1:2018 Annex A, Chronic Toxicity test (as Chronic GLP Animal Study) is not required as one of the biological endpoints. However, in-lieu of the Chronic Toxicity test, Subacute Toxicity test (as Subacute GLP Animal Study) was carried out. For the Subacute GLP Animal Study, refer to test report DY24080287E attached to this eSTAR.

Results of the Subacute GLP Animal Study are the following:
1. Clinical Observations - There were no clinical observations that indicated systemic toxicity caused by the test or control samples.
2. Body Weight - Individual weight gain and group mean body weights for both male and female animals were similar between the test and control groups and there were no statistically significant differences. Animals gained weight during the course of the study.
3. Necropsy Observations - There were no macroscopic observations differences of the viscera that could be attributed to the test sample.
4. Organ Weights - Individual organ weights and organ to body weight ratios for both male and female animals were similar between the test and control sample groups and there were no statistically significant differences.
5. Clinical Pathology - The hematology and clinical chemistry values showed no evidence of systemic toxicity.
6. Microscopic Evaluation - Microscopic findings in the saline group and oil group showed no evidence of a systemic toxicity related to the test sample response

Bench and performance testing of Pulmonary Artery Monitoring Catheter were carried out at t=0 and equivalent t=3 years years using accelerated ageing conditions using n=60 at 95/95 confidence/reliability intervals. In all test frequency, it showed that Pulmonary Artery Monitoring Catheter could meet the specifications and requirements.
No clinical testing was carried out for Pulmonary Artery Monitoring Catheter.

Not Applicable

There were no deviations to the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR Part 58) and OECD Series on Principles of Good Laboratory Practice (GLP) noted during the course of the study.

All the performed biocompatibility tests and the GLP Animal Study passed all the criteria according to the test standards. It is demonstrated that Bioptimal Pulmonary Artery Monitoring Catheter is safe for use according to its intended use and is compliant to the overall requirements of ISO 10993-1:2018.
With the combined results from bench/performance test, GLP animal study, it is concluded that the subject device is as safe and effective as the predicate device and performs according to its intended purpose. The subject device is substantially equivalent to the referenced predicate device.