June 15, 2025

Bioptimal International Pte. Ltd.
Francis Joey Eduave
Official Correspondent
36 Jalan Tukang #02-02
Singapore, Singapore 619266
Singapore

Re: K242863
Trade/Device Name: Bioptimal Bipolar Pacing Catheter
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular permanent or temporary pacemaker electrode
Regulatory Class: Class II
Product Code: LDF
Dated: May 12, 2025
Received: May 15, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2025.06.15 13:07:52 -04'00'

Sara Royce
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
OHT2: 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242863

Device Name

Bioptimal Bipolar Pacing Catheter (
BP2502-10, BP2502CS-10, BPX2502-10, BPX2502CS-10.)

Indications for Use *(Describe)*

Bioptimal Bipolar Pacing Catheters are indicated for use in temporary, transvenous, right ventricular pacing.

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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510(K) Summary for K242863

Submitter:	**Bioptimal International Pte. Ltd.** (Formerly known as Biosensors International Pte Ltd) 36 Jalan Tukang #02-02, Singapore 619266
Product Trade Name:	**Bioptimal Bipolar Pacing Catheter**
Common Name:	Temporary Cardiac Pacing Catheter
Classification Name:	Cardiovascular permanent and temporary pacemaker electrode
Classification:	Class 2 (**Reference:** 21 CFR 870.3680)
Product Code:	LDF
Predicate or legally marketed device:	**Pacel™ Flow Directed Pacing Catheter** Marketed by Abbott Laboratories (Previously known as St. Jude Medical) **510k number:** K161873
Date prepared:	June 13, 2025

Device Description:

Bioptimal's Bipolar Pacing Catheter is made of radiopaque polyurethane catheter tubing at a usable length of 110 cm that allows the use of fluoroscopy for guiding the catheter during insertion or to verify its position when necessary. The catheter has radiopaque bands marked every 10 cm along their length to assist the physician in determining the depth of catheter insertion.

The Bipolar Pacing Catheter has an electrode lumen, which provides electrical conductor isolation from electrodes to the connector pins. It has two metal electrodes attached to the distal end of the catheter and the distal electrode forms its distal tip. The proximal electrode is 10 mm apart from the distal electrode.

Bipolar Pacing Catheters are available in two generic models: balloon-guided floatation (with balloon) and semi-floated (without balloon), with or without contamination shield. All models have the same basic design, construction and material. The balloon-guided models (BP2502-10 and BP2502CS-10) includes a latex balloon mounted between the distal and proximal electrodes and associated balloon lumen and tubing extension for inflating and deflating the balloon. The balloon is used for the advancement of the catheter tip by means of balloon flotation in the blood flow. The models with a contamination shield (BP2502CS-10 and BPX2502CS-10) have an expandable shield up to 110cm that provides a sterile environment for the enclosed catheter, and hence prevents the contamination of a catheter as it is inserted into and withdrawn from a body cavity or lumen.

Balloon guided models are supplied with a 1.0cc syringe for balloon inflation.

Bipolar Pacing Catheters are supplied sterile (through ethylene oxide sterilization), non- pyrogenic and are for single use only.

The catheter primary packaging: the catheter is packed in a blue thermoformed polystyrene tray and is covered with a clear APET cover held in place by snap buttons. White label printed with the product name, model ID, manufacturer and authorized representative's information, lot number, expiry date, UDI, symbols and other product information is pasted on the clear APET tray cover. The catheter tray is placed inside a sealed Tyvek bag which forms a single sterile barrier primary packaging.

The catheter is supplied sterile in a box of 5 units of single sterile barrier primary packaging with IFU.

Indications for Use:

Bioptimal Bipolar Pacing Catheters are indicated for use in temporary, transvenous, right ventricular pacing.

Technology Comparison:

Bioptimal Bipolar Pacing Catheter is technologically comparable to the predicate device **Pacel™ Flow Directed Pacing Catheter** marketed by Abbott Laboratories (previously known as St. Jude Medical). **Bioptimal Bipolar Pacing Catheter** models can come with balloon or without balloon, with contamination shield or without contamination shield.

The corresponding predicate device **Pacel™ Flow Directed Pacing Catheter** marketed by Abbott Laboratories (previously known as St. Jude Medical) have these features too.

BPI and Predicate device catheter material: Polyurethane (PU)

BPI and Predicate device balloon material: Latex Rubber

BPI and Predicate contamination shield material: PVC (not in contact with Body)

BPI and Predicate device sterilization Process: Ethylene Oxide (EO) Sterilization

Characteristics	Bioptimal Bipolar Pacing Catheter	Pacel™ Flow Directed Pacing Catheter
Catheter's Materials	Polyurethane (PU)	PU
Balloon material	Latex rubber	Latex
Contamination shield material	Polyvinyl Chloride (Not in contact with Body)	PVC (Not in contact with Body)
indications for use	Bioptimal Bipolar Pacing Catheters are indicated for use in temporary, transvenous, right ventricular pacing.	Indicated for use in temporary, transvenous, right ventricular pacing.
French size of catheter	4, 5, 6, and 7 French	4 French, 5 French, 6 French, 7 French
Length of Catheter	110 cm	110 cm

Non-Clinical and Clinical Tests Summary and Conclusions:

Bioptimal Bipolar Pacing 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.

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 Bioptimal Bipolar Pacing Catheter were carried out at t=0 and equivalent t=2 years / t=3 years using accelerated ageing conditions using n=60 at 95/95 confidence/reliability intervals. In all test frequency, it showed that Bioptimal Bipolar Pacing Catheter could meet the specifications and requirements.

A retrospective clinical data analysis was carried out for Bioptimal Bipolar Pacing Catheter using a single-center, single-arm, consecutive cases without omission at a hospital in China between March 2022 and December 2024. Results of this retrospective clinical data analysis are:
• 85 patients, average age 69 +/- 12, 58% male. Treatment was 6% for aortic valve procedures and 92% for arrhythmias.
• The primary effectiveness performance goal of Bioptimal Bipolar Pacing Catheter was met. The pacing success rate was 100% [95% Confidence Interval, 95.75% - 100.00%], p<0.0001.
• The primary safety performance goal of this device was also met. The complication-free rate was 100% [95% Confidence Interval, 95.75% - 100.00%], p<0.0001.
• There were no medical complication events, device functional defect events, or adverse events, such as perforation, dislodgement of electrodes, infections, loss of capture, loss of signal, cardiac tamponade, embolism, etc.
• The pacing rate was maintained throughout the duration of the indwelling catheter.

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's Bipolar Pacing Catheter is compliant to the overall requirements of ISO 10993-1:2018.

With the combined results from bench/performance test, GLP animal study and patient data analysis using Bioptimal Bipolar Pacing Catheter, it is concluded that the subject device is substantially equivalent to the predicate device.