February 26, 2025

Vygon Corporation
Chris Steinke
Quality Assurance and Regulatory Affairs Manager
2750 Morris Road, Suite A200
Lansdale, Montgomery, Pennsylvania 19446

Re: K241587
Trade/Device Name: pilot TLS
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS
Dated: May 31, 2024
Received: June 3, 2024

Dear Chris Steinke:

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
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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.

510(k) Number *(if known)*
K241587

Device Name
Pilot TLS

Indications for Use *(Describe)*
The Pilot TLS is indicated for use in positioning of PICCs. The Pilot TLS provides real-time catheter tip location information by displaying changes in the patient's cardiac electrical activity. Pilot TLS is indicated for use as an alternative method to chest X-ray or fluoroscopy confirmation of PICC tip placement in adult patients.
Note: Limited, but not contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P-wave:
- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-Driven Rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of additional method is necessary to confirm catheter tip location.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

VYGON CORPORATION
2750 Morris Road
Lansdale
Montgomery
PA 19446 United States
Phone: (603)743-5988
Contact Person: Chris Steinke, Director of Quality Assurance, Regulatory Affairs, and Engineering
Initial Date Prepared: 31st May 2024

The device is manufactured by Medwin which is the legal manufacturer.

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Tél.: +33 (0) 4 67 95 74 72
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Name of Device

Pilot TLS

Common or Usual Name

Percutaneous, implanted long-term intravascular catheter.

Classification Name

Class II, 21 CFR Section 880.5970- LJS (Catheter, intravascular, Therapeutic Long-Term Greater Than 30 Days).

Predicate Device

C3 Wave (K170934) manufactured by Medcomp (dba Medical Components Inc.).

Device Description

Pilot TLS is designed to support guidance and tip positioning of Peripherally Inserted Central Catheters (PICCs) of at least 3 Fr in size. Pilot TLS provides real-time catheter tip location information by using the patient's cardiac electrical activity and is indicated for use as an alternative method to chest X-ray and fluoroscopy for PICC tip placement confirmation for adults. The device includes a medical tablet preloaded with Pilot software, a Pilot TLS module, an ECG cable accessory, and a Vygocard accessory.

The device is only provided in one configuration, and non-sterile. The system is composed of:

- A medical tablet with a kickstand attached on the back
- The medical tablet's power supply
- A Pilot TLS module attached to a USB-A cable
- A stabilization base (option to maintain the black ECG lead for its connection to Vygocard saline connector
- An ECG cable with 4 leads (red, white, green, black)
- 2 USB flash drives

Vygocard is an accessory provided sterile.

Indications for Use

The Pilot TLS is indicated for use in positioning of PICCs. The Pilot TLS provides real-time catheter tip location information by displaying changes in the patient's cardiac electrical activity. Pilot TLS is indicated for use as an alternative method to chest X-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: Limited, but not contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P-wave:

- Atrial fibrillation

- Atrial flutter

- Severe tachycardia

- Pacemaker-Driven Rhythm

- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of additional methods is necessary to confirm catheter tip location.

Comparison of Technological Characteristics with The Predicate Device:

The subject and predicate devices have similar technological characteristics, and the minor differences do not raise any new issues of safety and effectiveness. The following characteristics are identical between the subject device and predicate devices:

- Fundamental technology
- Principle of operation
- Technological characteristics (material, sterilization)

The design comparison matrix below summarizes the technological differences between Pilot TLS and the predicate devices.

Criterion	Proposed Device: Pilot TLS	Predicate Device: C3 Wave (K170934)	Substantially Equivalent comparison
ECG signal transmission	Pilot TLS uses an adaptor for the ECG signal transmission. This adaptor can be either an ECG clip cable, as the predicate, or Vygocard, which is a saline column connector.	C3 Wave uses a stylet. Indeed, C3 wave uses a "ECG Clip Cable" to transmit the patient's ECG waves by connecting the PICC stylet to the Hub. Connections are made using the stereo jack (for the Hub) and the alligator clip (for the PICC stylet). The alligator clip is placed on the metal portion of the stylet wire.	Same and different methods, C3 wave only works with conductive metal stylet for ECG signal transmission, while Pilot TLS works with both conductive metal stylet and a saline column connector.
ECG Data Transmission	Pilot TLS uses an USB cable for the ECG data transmission between the Pilot TLS patient module and the Operator module (tablet).	C3 Wave uses wireless technology (Bluetooth) instead of a USB cable for the ECG data transmission between the Patient module (Hub) and the tablet.	Similar
Computer Platform	Pilot TLS uses a mobile platform (Windows tablet)	C3 Wave uses a mobile platform (iPad tablet)	Similar
Software: Method for catheter tip placement confirmation	Catheter tip placement confirmation via the patient's cardiac electrical activity, based upon identification of a maximum P-wave in the patient's intravascular ECG signal collected via the saline column or the conductive stylet with 3Fr or larger CVADs	Catheter tip placement confirmation via the patient's cardiac electrical activity, based upon identification of a maximum P-wave in the patient's intravascular ECG signal collected via conductive stylets.	Similar: C3 wave only works with conductive metal stylet for ECG signal transmission, while Pilot TLS works with both conductive metal stylet and a saline column connector.
Components	• ECG Cable • Pilot TLS Patient Module • Tablet computer with its medical AC power supply • Pilot TLS Software • VYGOCARD (can be replaced by an ECG clip cable if the user prefers to use a metal stylet method) • Stabilization base	• C3 Wave Hub • iPad + C3 Wave software application • Remote • ECG Clip Cable • ECG Snap Lead Set • Power Supply	Similar

Table 1: Design Comparison matrix

Non-Clinical Performance Data

Testing verifying the performance requirements of Pilot TLS system was conducted and included in this premarket notification and the results support substantial equivalence.

Testing included:

- IEC 60601-1, 3rd Edition – Electrical Safety
- IEC 60601-1-2, 3rd Edition – Electromagnetic Compatibility
- Software Verification and Validation Testing
- Human Factors: A human factors study assessing the usability of the Pilot TLS was conducted. The study utilized independent clinician participants to assess the primary operating functions of the proposed device against the predetermined usability criteria.
  The results of the human factors study were compiled and assessed in accordance with CDRH guidance, *Applying Human Factors and Usability Engineering to Medical Devices – Guidance for Industry and Food and Drug Administration Staff* (February 3, 2016) as well as with IEC 62366-1: *Medical devices – Part 1: Application of usability engineering to medical devices.*

Testing verifying the performance requirements of the Vygocard was conducted and included in this premarket notification and the results support substantial equivalence.

Testing included:

- Biocompatibility: According to the requirements identified in ISO 10993-1, biocompatibility testing on the patient contacting devices subject to this premarket notification is included. Testing was conducted for the assessment of cytotoxicity (ISO 10993-5), hemocompatibility (ISO 10993-4), sensitization and irritation (ISO 10993-10), and pyrogenicity of the Vygocard.
- ISO 10555-1: Intravascular catheters Sterile and single-use catheters for the corrosion
- ISO 80369-7
- ISO 80369-20

Clinical Performance Data

No human clinical data was provided to support substantial equivalence.

Substantial Equivalence

Pilot TLS is substantially equivalent to the predicate devices. Pilot TLS has the same intended use as the predicate device. The subject and predicate device are intended to display patient's ECG waveforms to provide real time tip location information of a central venous catheter,

Regarding the technological characteristics, the subject device and the predicate incorporate both electronic circuitry and software to acquire and display the patient's intravascular and external ECG waveforms to facilitate the confirmation of final central catheter tip placement as an alternative to radiographic confirmation.

Therefore, Pilot TLS is substantially equivalent to the currently marketed predicate device.

Conclusion

The information included in this premarket notification supports the substantial equivalence of the subject Pilot TLS to the C3 Wave Form. The subject device has the same intended use, similar indications for use and incorporates the same fundamental technology as the legally marketed predicate devices to which it was compared.

Performance and biocompatibility data were included to verify the performance of the subject device against its physical design, functional, and safety requirements. The results of the testing included in this premarket notification support a determination of substantial equivalence.