



September 21, 2026

Zylox Medtech Co., Ltd.
Siran Wu
Regulatory Affair Specialist
Rm. 406, 4th Floor, Block B, # 270, Shuyun Rd.
Cangqian Sub-District, Yuhang District
Hangzhou, Zhejiang 311121
China

Re: K260416

Trade/Device Name: ZYLOX Hippo PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: August 17, 2026
Received: August 18, 2026

Dear Siran Wu:

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,

GREGORY W.

O'CONNELL -S

Digitally signed by GREGORY W.
O'CONNELL -S
Date: 2026.09.21 13:51:17 -04'00'

Gregory O'Connell

Assistant Director

DHT2C: Division of Coronary and

Peripheral Intervention Devices

OHT2: 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.

K260416

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Please provide the device trade name(s).

?

ZYLOX Hippo PTA Balloon Dilatation Catheter

Please provide your Indications for Use below.

?

The ZYLOX Hippo PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature including upper extremity, renal, iliac, and infra-inguinal vessels and the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The ZYLOX Hippo PTA Balloon Dilatation Catheter is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

This summary of 510(K) is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Sponsor Identification

Zylox Medtech Co., Ltd.

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2. Primary Correspondent

Zylox Medtech Co., Ltd.

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Contact Person: Siran Wu

Position: Regulatory affair specialist

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E-mail: sr.wu@zyloxmedical.com

3. Date Prepared: September 19, 2026

4. Proposed Device Information

Trade/Device name: ZYLOX Hippo PTA Balloon Dilatation Catheter

Classification Name: Catheter, Angioplasty, Peripheral, Transluminal

Classification: II

Product Code: LIT

Regulation Number: 21 CFR 870.1250

Regulation Name: Percutaneous Catheter

Review Panel: Cardiovascular

5. Predicate Device Information

Identification	Manufacturer	Device Name	510(K) Number
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Predicate Device	Boston Scientific Corporation	Athletis™ PTA Balloon Dilatation Catheter	K201170
Reference Device	C.R. Bard, Inc.	Conquest™ 40 PTA Dilatation Catheter	K212588

6. Device Description

The ZYLOX Hippo PTA Balloon Dilatation Catheter is a high performance over-the-wire (OTW) balloon catheter consisting of distal tip, radiopaque markers, balloon, catheter, catheter hub and catheter hub strain reinforcement. The proprietary non-compliant, low profile balloon is designed to provide consistent balloon diameters and lengths even at high pressures. The catheter features a dual-lumen shaft ending in a Y-connector catheter hub with luer lock fittings. One of the port connects to a balloon inflation device for balloon inflation and deflation, while the other port is used to deliver the catheter over a 0.035 inch (0.89 mm) guidewire. Two radiopaque marker bands, in conjunction with fluoroscopy, aid in the visualization of the balloon. The catheter includes a soft and tapered distal tip to facilitate advancement of the catheter to and through the treatment site. The balloon catheter is available in working lengths of 50 cm, 75 cm, and 135 cm to accommodate various anatomical requirements.

7. Indications for Use

The ZYLOX Hippo PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature including upper extremity, renal, iliac, and infra-inguinal vessels and the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The ZYLOX Hippo PTA Balloon Dilatation Catheter is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature.

8. Technological Comparison

The proposed device, ZYLOX Hippo PTA Balloon Dilatation Catheter is identical to the predicate device in the following aspects:

No.	Items	Comment	Discuss
1	Indication for use	Same	/
2	Device Photo	Similar	/
3	Balloon surface	Similar	/
4	Device configuration	Different	The materials of the proposed device that come into direct or indirect contact with the human body have long history in medical use, and biocompatibility evaluation results showed that no biological response to direct or indirect contacting materials. Therefore, this difference would not raise new questions of safety.
5	Guidewire Compatibility/	Same	/
6	Sheath Compatibility	Same	/
7	Catheter length	Same	/

8	Catheter Outer Diameter	Similar	The outer diameter of the proposed device is slightly smaller than that of the predicate devices, which facilitates improved deliverability. This reduction is not expected to impact the device performance negatively. Bench testing confirmed that the proposed catheter design performs comparably to the predicate device. The difference does not raise new questions of safety.
9	Balloon Lengths	Same	/
10	Balloon Diameters	Same	/
11	Nominal Pressure	Same	/
12	Rated Burst Pressure	Same with reference device	The proposed device has a rated burst pressure range matching the reference device and partially overlapping with the predicate. Bench testing was conducted to demonstrate inflation performance to RBP.
13	Coating Material	Same with reference device	The Result of Bench testing and Biocompatibility testing showed that the proposed device does not raise new questions of safety
14	Sterilization Method	Same	/
15	SAL	Same	/

9. Non-Clinical Performance Data

The following testing was conducted to validate and verify that the subject device was substantially equivalent to the predicate devices. All data met pre-determined acceptance.

8.1 Biocompatibility Tests

- *Cytotoxicity*
- *Irritation/ Intracutaneous Toxicity*
- *Sensitization*
- *Systemic Injection*
- *Material Mediated Pyrogenicity*
- *Hemolysis*
- *Complement Activation*
- *Coagulation(PTT)*
- *Leukocyte and Platelet Counts*

8.2 Performance Tests

Surface, Balloon Surface, Distal Tip, Dimension, Compatibility, Stimulated Use, Freedom from Leakage, Balloon compliance, Balloon Inflation and Deflation Time, Balloon Fatigue, Balloon Rated Burst Pressure, Hydratable Catheter, Peak Tensile Force, Catheter Hub, Crossing profile, Flexibility and Kink, Torque Strength.

8.3 Sterility, Shipping and Shelf Life

The sterilization method has been validated per ISO 11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the ZYLOX Hippo PTA Balloon Dilatation Catheter is determined based on stability studies which includes accelerated aging.

8.4 Animal Study

N/A

8.5 Clinical Evidence

N/A

10. Substantial Equivalent Conclusions

ZYLOX Hippo PTA Balloon Dilatation Catheter has the same intended use, similar technological characteristics as the predicate device. Moreover, non-clinical testing contained in this submission demonstrates substantial equivalence to predicate..

In conclusion, ZYLOX Hippo PTA Balloon Dilatation Catheter is substantial equivalent to the predicate device.