August 28, 2024

Ningbo DIZEGENS Medical Science Co., Ltd.
Zhang Wenwei
Vice General Manager
Floor 3&4, Building A4, No. 777, Binhai 4th Road
Qianwan New Area.
Ningo, Zhejiang 315336
China

Re: K232388
Trade/Device Name: High Pressure Tubing
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: DXT

Dear Zhang Wenwei:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 21, 2023. Specifically, FDA is updating this SE Letter due to a typographical error in the company name listed in the letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shruti Mistry, Assistant Director for Injection Devices at 301-796-6605 or Shruti.Mistry@fda.hhs.gov.

Sincerely,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

November 21, 2023

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Regulation Name: Angiographic injector and syringe
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Product Code: DXT
Dated: October 27, 2023
Received: October 27, 2023

Dear Zhang Wenwei:

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.

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,

Juliane C. Lessard -S

Juliane C. Lessard
Director, Division of Drug Delivery and
General Hospital Devices,
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Office of Product Evaluation and Quality
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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)*
K232388

Device Name
High Pressure Tubing

Indications for Use *(Describe)*
High Pressure Tubing is indicated for use in PTCA surgery to connect the angiographic catheter and the angiographic syringe to deliver contrast media.

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.

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Food and Drug Administration
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PRAStaff@fda.hhs.gov

"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

1. Submitter/510(k) Holder

Submission: Traditional 510(k) Premarket Notification
Submitter: Ningbo DIZEGENS Medical Science Co., Ltd.
Address: Floor 3&4, Building A4, No. 777, Binhai 4th Road, Qianwan New Area, Ningbo, Zhejiang Province, P.R. China. 315336
Contact Person: Zhang Wenwei, Vice General Manager
Telephone: +86-574-82359758
Telefax: +86-574-82359059
Email: edwardzhang@dizegens.com
Date prepared: Oct 27, 2023

2. Subject Device

Device Trade Name: High Pressure Tubing
Device Common Name: High Pressure Tubing
Regulatory Name: Angiographic injection and syringe
Regulation Number: 21 CFR 870.1650
Product Code: DXT
Regulatory Class: II
Review Panel: Cardiovascular
510(k) Number: K232388

3. Predicate Device

The High Pressure Tubing is substantially equivalent to the following legally marketed predicate device.

510(k) Number	Trade Name	Manufacturer
K170014	High Pressure Tubing	Shanghai Kindly Medical Instruments Co., Ltd.

4. Device Description

High Pressure Tubing is designed as a connecting line for injection of contrast media during coronary angiographic procedures. The device has a pressure resistance of 1200psi (8.3MPa); It is divided into two series according to the luer connector combination. ETM series consists of tubing and rotating male luer connecters, and the ETF series consists of tubing and rotating male luer connector, female luer connecter; The rotating male luer connector and female luer connector are made of polycarbonate and silica gel; The tubing is made of polyurethane, and the middle of the tube wall also contains nylon braided wire, which does not contact with outside. The High Pressure Tubing is for single use only, non-pyrogenic, sterilized by EO gas and the sterilization process is validated. The High Pressure Tubing has 12 models and the differences for each model are listed in the following table 1.

Table 1 Models of High Pressure Tubing

No.	Model		Length(cm)	Luer Connector Combination	Pressure Resistance(psi)
1	ETF Series	ETF-025	25	Rotating Male Luer Connector + Female Luer Connector	1200
2		ETF-050	50		
3		ETF-075	75		
4		ETF-100	100		
5		ETF-125	125		
6		ETF-150	150		
7	ETM Series	ETM-025	25	Rotating Male Luer Connector +Rotating Male Luer Connector	
8		ETM-050	50		
9		ETM-075	75		
10		ETM-100	100		
11		ETM-125	125		
12		ETM-150	150		

5. Indications for Use

High Pressure Tubing is indicated for use in PTCA surgery to connect the angiographic catheter and the angiographic syringe to deliver contrast media.

6. Comparison of Technological Characteristics with the Predicate Device

The subject device, High Pressure Tubing, and the predicate device, High Pressure Tubing of Shanghai Kindly medical instruments Co., Ltd. have different intended use, indications for use, principle of operation but the differences do not raise additional concerns of safety and effectiveness. The subject device and predicate device have identical characteristics including components, technology and design, pressure rating, conical fitting, flexible, biocompatibility, sterilization, sterile, single use.

Difference in technology characteristics between the subject device, High Pressure Tubing, and predicate device, High Pressure Tubing, are provided in Table 2.

Table 2 Technological Characteristics Comparison

Description	High Pressure Tubing (Predicate Device)	High Pressure Tubing (Subject Device)	Comparison to predicate device
510(k) Number	K170014	K232388	N/A
Regulation Number	21 CFR 870.1650	21 CFR 870.1650	Same
Regulatory Name	Angiographic injection and syringe	Angiographic injection and syringe	Same
Product Code	DXT	DXT	Same
Regulatory Class	II	II	Same

Intended Use	The High Pressure Tubing is indicated for use as a connecting line for injection of contrast media or saline during coronary angiographic procedures.	High Pressure Tubing is indicated for use in PTCA surgery to connect the angiographic catheter and the angiographic syringe to deliver contrast media.	Different[1]
Indications for Use	The High Pressure Tubing is indicated for use as a connecting line for injection of contrast media or saline during coronary angiographic procedures	High Pressure Tubing is indicated for use in PTCA surgery to connect the angiographic catheter and the angiographic syringe to deliver contrast media.	Different[1]
Principle of Operation	Manual connect the male luer or rotating male luer of high pressure with other catheter device.	1. Check whether the package is complete; Do not use if the unit package has been damaged; 2. Open the package and check the product., do not use if the product is damaged or incomplete; 3. Connect the luer connector with the corresponding device; 4. After the infusion of liquid, check whether there is leakage at the connecting position; If there is leakage, it is necessary to check whether the connection of the device is loose and reconnect it firmly, or replace it with a new product.	Different[2]
Technology and Design	Designed to multiple length and connector types. PU tubing with polyamides liner for 1200psi	Designed to multiple length and connector types. PU tubing with nylon braided wire for 1200psi.	Different [3]
Components	Tubing, female/male luer, rotating adapter	Tubing, Female Luer Connector, Rotating Male Luer Connector	Same
Size	30cm,60cm,90cm,120cm,150cm,	25cm,50cm,75cm,100cm,125cm,150cm,	Different[4]
Pressure Rating	1200psi	1200psi	Same
Conical Fitting	Comply with ISO 80369-7-2021	Comply with ISO 80369-7: 2021	Same
Flexible	Yes	Yes	Same
Biocompatibility	ISO 10993 series	ISO 10993 series	Same
Sterilization	EO sterilization	EO sterilization	Same
Sterile	Yes	Yes	Same
Single Use	Yes	Yes	Same

Note[1]: The subject device is intended to deliver contrast media in PTCA surgery same as predicate device, but not deliver saline which have significant decrease in risk compared to predicate device. Therefore, this difference does not raise new or different questions of safety and effectiveness.

Note[2]: In Principle of Operation, the step 3 of subject device is identical with the operation of predicate device. In addition, more check steps have introduced to the operations of subject device, including step 1, 2 and 4, which

could decrease the risks in the operation. Therefore, this difference does not raise new or different questions of safety and effectiveness.

Note[3]: In Technology and Design, PU tubing with Nylon braided wire is the identical material with PU tubing with Polyamides liner that it just is the different description. This difference does not raise new or different questions of safety and effectiveness.

Note[4]: The sizes of predicate device are 30 to 150cm with 30cm intervals, and the sizes of subject device are 25 to 150cm with 25cm intervals. The minimum length of 25cm is suitable for potential clinical demand, and less length is meaning lower risk. The two devices have same longest configuration, 150cm, which is the most challenge size for characteristics. Therefore, this difference does not raise new or different questions of safety and effectiveness.

Conclusion: The differences between the subject and the predicate device do not raise additional questions of safety and effectiveness.

7. Performance Data

The subject device, High Pressure Tubing, was subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters:

Biocompatibility Testing:

Per ISO 10993-1: 2018 and FDA guidance, the following tests were performed to ensure the biocompatibility of the subject device.

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Material mediated pyrogenicity
- Acute systemic toxicity
- Hemocompatibility

Bench Testing:

Per ISO 8536-4: 2019, ISO 80369-7: 2021, ISO 80369-20: 2015, etc., the following tests were performed to ensure performance/functionality of the subject device.

- Visual
- Dimension
- Particulate Contamination
- Leakage
- Tensile Strength
- 6% Luer Connector
- EO Residual
- ECH Residual
- Sterility
- Endotoxin
- Pouch Visual
- Pouch Seal Peel Strength

- Pouch Integrity

Clinical Tests:

Clinical tests were not required to demonstrate performance of High Pressure Tubing. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests:

Animal tests were not required to demonstrate performance of High Pressure Tubing. Product functionality has been adequately assessed by non-animal tests.

8. Conclusions

Based on the information presented in this 510(k) premarket notification, the subject device, High Pressure Tubing is considered substantially equivalent to the predicate device, High Pressure Tubing of Shanghai Kindly Medical Instruments Co., Ltd.