February 28, 2024

Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH
℅ Jennifer Kiblinger
Scientific Director
Diapharma Group, Inc.
8948 Beckett Road
West Chester, Ohio 45069

Re: DEN230024
Trade/Device Name: Technozym ADAMTS13 Activity
Regulation Number: 21 CFR 864.7297
Regulation Name: ADAMTS13 activity test system
Regulatory Class: Class II
Product Code: SAC
Dated: April 6, 2023
Received: April 6, 2023

Dear Jennifer Kiblinger:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Technozym ADAMTS13 Activity, a prescription device with the following indications for use:

> The Technozym ADAMTS13 Activity assay is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative determination of ADAMTS13 activity in platelet poor human citrated plasma. The assay is intended to be used in conjunction with other clinical and laboratory findings as an aid in the diagnosis of thrombotic thrombocytopenic purpura (TTP) in adult and pediatric patients being evaluated for thrombotic microangiopathy (TMA).

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Technozym ADAMTS13 Activity, and substantially equivalent devices of this generic type, into Class II under the generic name ADAMTS13 activity test system.

FDA identifies this generic type of device as:

> **ADAMTS13 activity test system**: An ADAMTS13 activity test system is a qualitative or quantitative in vitro diagnostic device intended to detect ADAMTS13 activity in human blood specimens collected from patients being evaluated for thrombotic microangiopathy. This device is

indicated to aid in the diagnosis and management of patients being evaluated for thrombotic thrombocytopenic purpura in conjunction with other clinical and laboratory findings.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 6, 2023, FDA received your De Novo requesting classification of the Technozym ADAMTS13 Activity. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Technozym ADAMTS13 Activity into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Technozym ADAMTS13 Activity can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Clinical action based on false positive results may lead to inappropriate patient management, or unnecessary treatments.	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements and performance characteristics.
Clinical action based on false negative results may lead to delayed diagnosis, misdiagnosis, or discontinuation of treatment.	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements and performance characteristics.

In combination with the general controls of the FD&C Act, the ADAMTS13 activity test system is subject to the following special controls:

1. Design verification and validation must include the following:

    (i) Detailed documentation of data that demonstrates device clinical performance for all intended clinical uses, including all of its indications for use, as determined to be appropriate by FDA;

    (ii) Documentation of data demonstrating that the device output is free from clinically significant interference, as determined by FDA, from endogenous and exogenous interferents associated with the target population(s), and interferents that are specific for, or related to, the technology or methodology of the device;

    (iii) Documentation of data demonstrating that the precision performance is clinically appropriate, as determined by FDA, for the intended use specimen types. Precision performance must be evaluated using clinical specimens with different ADAMTS13 activity levels including near medical decision points and throughout the expected range of the test system.

2. The labeling required under 21 CFR 809.10(b) must include limiting statements indicating, as applicable:

    (i) That the device should only be used in conjunction with other clinical and laboratory findings;
    (ii) A statement explaining that the device has not been evaluated to guide the use of monitoring or to guide treatment of thrombotic thrombocytopenic purpura;
    (iii) A statement explaining that ADAMTS13 activity levels above the clinically relevant diagnostic cut-off should not exclude the diagnosis of thrombotic thrombocytopenic purpura in patients with high clinical suspicion.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the ADAMTS13 activity test system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Shuchi Gupta at shuchi.gupta@fda.hhs.gov.

Sincerely,

Takeesha Taylor-bell -S

for

Lea Carrington
Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health