September 29, 2023

ProciseDx Inc.
Kurtis Bray
Senior Director of Clinical Development and Regulatory Affairs
9449 Carroll Park Drive
San Diego, California 92121

Re: DEN210056
Trade/Device Name: Procise IFX
Regulation Number: 21 CFR 862.3115
Regulation Name: Anti-tumor necrosis factor alpha monoclonal antibody test system for inflammatory bowel disease
Regulatory Class: Class II
Product Code: QXT
Dated: April 14, 2023
Received: April 14, 2023

Dear Kurtis Bray:

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 Procise IFX with the following indications for use:

> The Procise IFX assay is a time-resolved fluorescence energy transfer immunoassay for the quantitative determination of infliximab levels in venous serum in patients undergoing infliximab therapy, using the ProciseDx Analyzer.
>
> Measurements obtained by this assay can be used to detect infliximab as an aid in the management of patients with inflammatory bowel diseases (IBD): Crohn's disease and ulcerative colitis being treated with infliximab. The test is intended for use in a clinical laboratory.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Procise IFX, and substantially equivalent devices of this generic type, into Class II under the generic name anti-tumor necrosis factor alpha monoclonal antibody test system for inflammatory bowel disease.

FDA identifies this generic type of device as:

> **Anti-tumor necrosis factor alpha monoclonal antibody test system for inflammatory bowel disease**. An anti-tumor necrosis factor alpha antibody test system is an in vitro diagnostic device intended for the measurement of an anti-tumor necrosis factor alpha monoclonal antibody as an aid in the management of patients with Crohn's disease or ulcerative colitis.

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 December 8, 2021, FDA received your De Novo requesting classification of the Procise IFX. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Procise IFX 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 Procise IFX 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
Incorrect test results	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements.
Incorrect interpretation of test results	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements.

In combination with the general controls of the FD&C Act, the Anti-Tumor necrosis factor alpha monoclonal antibody test system for inflammatory bowel disease is subject to the following special controls:

(1) Design verification and validation must include the following:
   (i) Detailed documentation of studies that demonstrate the analytical performance of the device for its intended use, including for each analyte and device output. These studies must demonstrate analytical performance for each monoclonal antibody analyte and device output that is adequate to support all intended clinical uses, including all of its indications for use, and testing environments. These studies must include: precision, reproducibility, linearity, accuracy, high dose hook effect, sample stability, detection limits (including limit of blank, limit of detection, and limit of quantification) and analytical specificity studies, or alternative approaches determined to be appropriate by FDA.

   (ii) Detailed documentation of data that is adequate to support the accuracy of the device and/or device performance for all intended clinical uses, including all of its indications for use, as determined to be appropriate by FDA.

   (iii) Detailed documentation demonstrating traceability of the device to an internationally recognized reference material, as determined to be appropriate by FDA.

(2) The labeling required under 21 CFR 809.10(b) must include limiting statements including the following:
   (i) The device should not be used with conditions other than Crohn's disease or ulcerative colitis.
   (ii) The test result is intended as an aid in the management of the patient, and not to be used to replace clinical judgment.

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 anti-tumor necrosis factor alpha monoclonal antibody test system for inflammatory bowel disease 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 Joseph Cleveland at Joseph.Cleveland@fda.hhs.gov.

Sincerely,

Marianela Perez-torres -S

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