May 9, 2025

Teal Health, Inc.
Trena Depel
VP, Regulatory, Clinical, Quality
1012 Torney Ave
San Francisco, California 94129

Re: DEN240045
Trade/Device Name: Teal Wand
Regulation Number: 21 CFR 866.2920
Regulation Name: Device for home collection and transportation of clinical specimens by lay users for infectious disease testing
Regulatory Class: Class II
Product Code: SEP
Dated: August 27, 2024
Received: August 27, 2024

Dear Trena Depel:

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 Teal Wand, a prescription device with the following indications for use:

> The Teal Wand is a device for the self-collection of vaginal specimens for the purpose of collecting and transporting specimens for use in an FDA approved HPV molecular assay with which the collection device has been validated.
>
> The Teal Wand can be used at-home or in any private setting. Specimens can be collected, stored, and shipped dry in an empty vial.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Teal Wand, and substantially equivalent devices of this generic type, into Class II under the generic name device for home collection and transportation of clinical specimens by lay users for infectious disease testing.

FDA identifies this generic type of device as:

> **Device for home collection and transportation of clinical specimens by lay users for infectious disease testing**. A device for home collection and transportation of clinical specimens by lay users for infectious disease testing is a device intended for use by lay users in home settings or similar

environments for the collection and transportation of clinical specimens for infectious disease testing using in vitro diagnostic tests.

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 August 27, 2024, FDA received your De Novo requesting classification of the Teal Wand. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Teal Wand 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 Teal Wand 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
Failure to collect and transport specimen	Certain design verification and validation Certain labeling information including limiting statements
Insufficient specimen quantity and quality	Certain design verification and validation Certain labeling information including limiting statements
Injury to lay users	Certain design verification and validation

In combination with the general controls of the FD&C Act, the device for home collection and transportation of clinical specimens by lay users for infectious disease testing is subject to the following special controls:

(1) The intended use of the device must only include indications for collection and transport of specimen types that are appropriate, as determined by FDA, for collection by lay users in home settings or similar settings.

(2) The device must not be intended for use with in vitro diagnostic tests for the purpose of detecting pathogens that lead to unacceptable levels of harm (for example, high morbidity or mortality) if used with specimens collected by lay users.

(3) The device must be used to only collect the indicated specimen type(s) that have been validated for use with the FDA approved, cleared, or 510(k) exempt in vitro diagnostic infectious disease test(s).

(4) Design verification and validation documentation must include appropriate design inputs and design outputs that are essential for the proper functioning of the device for its intended use, including all of its indications for use, and must include the following:

(i) Documentation demonstrating that appropriate measures, as determined by FDA, are in place (e.g., validated device design features and specifications) to ensure that the device reproducibly and reliably collects and transports human specimens of sufficient yield and quality suitable for downstream testing, as appropriate for its intended use. At a minimum, these measures must include:

(A) Documentation and data demonstrating that clinical specimens collected with the device result in acceptable performance for each type of claimed use, such as in vitro diagnostic test, analyte, and anatomic sampling location or, alternatively an appropriate approach as determined by FDA, demonstrating that data for each type of claimed use is not needed;
(B) Documentation and data from analytical studies, such as limit of detection, inclusivity, interfering substances, as applicable;
(C) Documentation and data demonstrating collection device stability, including shelf life and shipping conditions;
(D) Documentation and data demonstrating specimen stability during handling, shipping, and storage, as applicable;
(E) Documentation and data demonstrating usability of the device in the hands of lay users and assessing user comprehension of the device's labeling; and
(F) Risk analysis and documentation demonstrating how risk control measures are implemented to address device system hazards, such as Failure Modes Effects Analysis and/or Hazard Analysis. This must include appropriate information and data that demonstrate the effectiveness of risk control measures and device robustness.

(ii) Data demonstrating sterility of any or all device components, as applicable.

(iii) Data demonstrating biocompatibility of patient-contacting device components, as applicable.

(5) Labeling must include the following:
(i) Instructions for specimen collection, packaging for shipping, transport to the testing site, educational information, and contact information for technical assistance with the collection device.

(ii) Warning and limitation statements including the following, as applicable:
(A) A statement that specimens collected with this device are only intended to be used with in vitro diagnostic tests with which the collection device has been validated.

(B) A statement that specimen quality is dependent on adherence to instructions for collection, shipping, and storage, and failure to follow these instructions can lead to incorrect test results;
(C) A statement that results obtained for specimens collected with this device do not substitute for a visit to a healthcare provider.

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 device for home collection and transportation of clinical specimens by lay users for infectious disease testing 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).

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.

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 Tania Sultana Bonny at 443-683-7327.

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health