



May 11, 2020

Advance Sentry Corporation
Leo Chui
Director of Operations
7155 Woodbine Ave., Suite 202
Markham, ON
Canada

Re: DEN190031

Trade/Device Name: NP Screen

Regulation Number: 21 CFR 866.3236

Regulation Name: Device to detect or measure nucleic acid from viruses associated with head and neck cancers

Regulatory Class: Class II

Product Code: OJY

Received: June 24, 2019

Dear Leo Chui:

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 NP Screen, a prescription device with the following indications for use:

NP Screen is a semi-quantitative in vitro diagnostic test that uses real-time PCR to determine the level of Epstein-Barr Virus Nuclear Antigen-1 (EBNA-1) DNA in nasopharyngeal cellular specimens collected using the NP Screen Trans-Oral Nasopharyngeal Brush. The test is intended for use in conjunction with endoscopy and other clinical information to assess the likelihood that EBV-associated nasopharyngeal carcinoma (NPC) is present. The test is indicated for use in adults of Chinese descent with signs and symptoms of nasopharyngeal carcinoma.

The NP Screen assay is a single-site assay performed at Primex Clinical Laboratories, Inc.

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. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the NP Screen, and substantially equivalent devices of this generic type, into Class II under the generic name device to detect or measure nucleic acid from viruses associated with head and neck cancers.

FDA identifies this generic type of device as:

Device to detect or measure nucleic acid from viruses associated with head and neck cancers. A device to detect or measure nucleic acid from viruses associated with head and neck cancers is an in vitro diagnostic test for prescription use in the detection of viral nucleic acid in nasopharyngeal or

oropharyngeal cellular specimens from patients with signs and symptoms of head and neck cancer. The test result is intended to be used in conjunction with other clinical information to aid in assessing the clinical status of virus-associated head and neck cancers and/or the likelihood that head and neck cancer is present.

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 June 24, 2019, FDA received your De Novo requesting classification of the NP Screen. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the NP Screen 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 NP Screen 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:

Identified Risks to Health	Identified Mitigations
False test results	Use of certain specimen collection and transport devices. Certain labeling information. Certain design verification and validation.
Failure to correctly interpret the test results	Certain labeling information.

In combination with the general controls of the FD&C Act, the device to detect or measure nucleic acid from viruses associated with head and neck cancers is subject to the following special controls:

1. Any device used for specimen collection and transport must be FDA-cleared, -approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of human specimens; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.

2. The labeling required under 21 CFR 809.10(b) must include, as determined to be appropriate by FDA:
 - i. An intended use statement that includes the following:
 - A. The analyte(s) detected by the device;
 - B. Data output of the device (qualitative, semi-quantitative, or quantitative);
 - C. The specimen types with which the device is intended for use;
 - D. The clinical indications appropriate for test use (e.g., in conjunction with endoscopy);
 - E. The intended use populations (e.g., signs and symptoms, ethnicity); and
 - F. The intended use location(s) (e.g., specific name and location of testing facility or facilities).
 - ii. A detailed device description, including reagents, instruments, ancillary materials, specimen collection and transport devices, controls, and a detailed explanation of the methodology, including all pre-analytical methods for processing of specimens.
 - iii. A detailed explanation of the interpretation of results.
 - iv. Limiting statements indicating:
 - A. The device is not intended for use in screening for head and neck cancer in asymptomatic populations.
 - B. Results of the device are not predictive of a patient's future risk of head and neck cancer.
 - C. Patients who test negative for the virus should be managed in accordance with the standard of care, based on the assessment of endoscopy and/or other clinical information by a licensed healthcare professional.
 - D. Results of the device are not intended to be used as the sole basis for determining the need for biopsy or for any other patient management decision.
3. Design verification and validation must include the following:
 - i. A detailed device description including pre-analytical specimen processing, assay technology, target region, primer/probe sequences, reagents, controls, instrument requirements, and the computational path from collected raw data to reported result.
 - ii. Detailed documentation and results from analytical performance studies including: characterization of the cut-off(s), limit of detection, limit of quantitation, precision (including multi-site reproducibility, if applicable), inclusivity, cross-reactivity, interference, carryover/cross-contamination, reagent stability, and specimen/sample stability, as determined to be appropriate by FDA.
 - iii. Detailed documentation of a clinical performance study that includes patients from the intended use population, including the clinical study protocol, with a pre-defined statistical analysis plan, and a clinical study report with testing results and results of all statistical analyses.

- iv. A detailed description of the impact of any software, including software applications and software incorporated in hardware-based devices, on the device's functions.

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 to detect or measure nucleic acid from viruses associated with head and neck cancers 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 Kim Davis at 301-796-1049.

Sincerely,

for

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