August 6, 2024

Hologic, Inc.
Attention: Howard Liu
10210 Genetic Center Drive
San Diego, CA 92121

Re: **BK231025**

Trade/Device Name:	Aptima® HIV-1 Quant Dx Assay
Regulation Number:	21 CFR 866.3958
Regulation Name:	Human Immunodeficiency virus (HIV) viral load monitoring test
Regulatory Class:	Class II
Product Code:	QUM
Dated:	July 1, 2024
Received:	July 2, 2024

Dear Howard Liu:

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.

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.**

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 801and Part 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Hira Nakhasi, PhD
Director
Division of Emerging and Transfusion
Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure: Indications for Use

Indications for Use

510(k) Number: BK 231025

Device Name: Aptima® HIV-1 Quant Dx Assay

Indications for Use:

The Aptima® HIV-1 Quant Dx assay is an in vitro nucleic acid amplification test (NAAT) for the detection and quantitation of human immunodeficiency virus type 1 (HIV-1) on the fully automated Panther® system and Panther Fusion® system. It is intended to be used as an aid in diagnosis for HIV-1 infection using appropriate HIV testing algorithms. The presence of HIV-1 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 is indicative of acute or primary infection.

The Aptima® HIV-1 Quant Dx assay may also be used as a supplemental test, when it is reactive, to confirm HIV-1 infection in an individual whose plasma or serum specimen is reactive with an approved assay with an indication as an aid in the diagnosis of HIV-1 infection.

The Aptima® HIV-1 Quant Dx assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in monitoring the effects of antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels. The Aptima® HIV-1 Quant Dx assay quantitates HIV-1 RNA groups M, N, and O over the range of 30 to 10,000,000 copies/ mL. One international unit is equivalent to 0.35 copies of HIV-1 RNA for the 3rd HIV-1 WHO International Standard (subtype B, NIBSC code: 10/152).

This assay is not intended to be used as a donor screening test for HIV-1. Performance of this test has not been evaluated for use in pregnant women or in a pediatric population.

Prescription Use _X_ ___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Blood Research and Review (OBRR)

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Division Sign-Off, Office of Blood Research and Review