Hologic, Inc.
Jon Kukowski
Regulatory Affairs Specialist
10210 Genetic Center Dr
San Diego, California 92121

Re: K231017
Trade/Device Name: Panther Fusion AdV/hMPV/RV Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OCC, OEM, OOI
Dated: April 7, 2023
Received: April 10, 2023

Dear Jon Kukowski:

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 (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 located 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

801 and 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,

Joseph Briggs -S

Joseph Briggs, Ph.D.
Deputy Branch Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231017

Device Name

Panther Fusion AdV/hMPV/RV Assay

Indications for Use *(Describe)*

The Panther Fusion® AdV/hMPV/RV assay is a multiplex real-time PCR (RT-PCR) in vitro diagnostic test for the rapid and qualitative detection and differentiation of Adenovirus (AdV), human Metapneumovirus (hMPV), and Rhinovirus (RV). Nucleic acids are isolated and purified from nasopharyngeal (NP) swab specimens obtained from individuals exhibiting signs and symptoms of a respiratory tract infection.

This assay is intended to aid in the differential diagnosis of Adenovirus, human Metapneumovirus, and Rhinovirus infections in humans. Negative results do not preclude Adenovirus, human Metapneumovirus, and Rhinovirus infections and should not be used as the sole basis for treatment or other management decisions. This assay is designed for use on the Panther Fusion system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Prepared on: 2023-05-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Hologic, Inc.
Applicant Address	10210 Genetic Center Dr San Diego CA 92121 United States
Applicant Contact Telephone	218-791-1313
Applicant Contact	Mr. Jon Kukowski
Applicant Contact Email	jonathan.kukowski@hologic.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Panther Fusion AdV/hMPV/RV Assay
Common Name	Respiratory viral panel multiplex nucleic acid assay
Classification Name	Respiratory Virus Panel Nucleic Acid Assay System
Regulation Number	866.3980
Product Code	OCC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172629	Panther Fusion AdV/hMPV/RV Assay	OCC

Device Description Summary

21 CFR 807.92(a)(4)

The Panther Fusion AdV/hMPV/RV assay is a multiplex real-time PCR (RT-PCR) in vitro diagnostic test for the rapid and qualitative detection and differentiation of Adenovirus (AdV) human Metapneumovirus (hMPV), and Rhinovirus (RV). Nucleic acids are isolated and purified from nasopharyngeal (NP) swab specimens obtained from individuals exhibiting signs and symptoms of a respiratory tract infection.

Nucleic acid capture and elution
Prior to processing and testing on the Panther Fusion system, specimens are transferred to a Specimen Lysis Tube containing specimen transport media (STM) that lyses the cells, releases target nucleic acid and protects them from degradation during storage. The Internal Control-S (IC-S) is added to each test specimen and controls via the working Panther Fusion Capture Reagent-S (wFCR-S). The IC-S in the reagent monitors specimen processing, amplification and detection. Capture oligonucleotides hybridize to nucleic acid in the test specimen. Hybridized nucleic acid is then separated from the specimen in a magnetic field. Wash steps remove extraneous components from the reaction tube. The elution step elutes purified nucleic acid. During the nucleic acid capture and elution step, total nucleic acid is isolated from specimens.

Elution transfer and RT-PCR
During the elution transfer step, eluted nucleic acid is transferred to a Panther Fusion reaction tube already containing oil and reconstituted mastermix. For RV, hMPV, and internal control targets, amplification occurs via RT-PCR. A reverse transcriptase step generates DNA copies of the target sequence. For AdV, target amplification occurs via PCR. For all targets, specific forward and reverse primers and probes amplify targets while simultaneously detecting and discriminating multiple target types via multiplex PCR. The Panther Fusion system compares the fluorescence signal to a predetermined cut-off to produce a qualitative result for the presence or absence of the analyte. The assay analytes (Adenovirus, human Metapneumovirus, Rhinovirus, and Internal Control) through specific gene targets (Hexon, Nucleocapsid, 5' UTR, and n/a, respectively) are detected in different channels of the Panther Fusion system (HEX, ROX, FAM, and RED677, respectively).

Assay Components
The reagents required to perform the Panther Fusion AdV/hMPV/RV assay are packaged and sold separately. There are 7 boxes containing 9 reagents which are required for sample processing. IA description of the components that are required to perform the Panther Fusion AdV/hMPV/RV assay are detailed below.

Box 1 - Panther Fusion AdV/hMPV/RV Assay Cartridges
Box 2 - Panther Fusion Extraction Reagent-S (contains Panther Fusion Capture Reagent-S and Panther Fusion Enhancer Reagent-S)
Box 3 - Panther Fusion Internal Control-S
Box 4 - Panther Fusion Reconstitution Buffer I
Box 5 - Panther Fusion Elution Buffer
Box 6 - Panther Fusion Oil
Box 7 - Panther Fusion AdV/hMPV/RV Assay Controls (Panther Fusion AdV/hMPV/RV Positive Control and Panther Fusion Negative Control)

In addition, select components can also be ordered in the following bundles:
• Panther Fusion Universal Fluids Kit: (contains Panther Fusion Oil and Panther Fusion Elution Buffer).
• Panther Fusion Assay Fluids I-S: (contains Panther Fusion Extraction Reagents-S, Panther Fusion Internal Control-S, and Panther Fusion Reconstitution Buffer I).

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Panther Fusion® AdV/hMPV/RV assay is a multiplex real-time PCR (RT-PCR) in vitro diagnostic test for the rapid and qualitative detection and differentiation of Adenovirus (AdV), human Metapneumovirus (hMPV), and Rhinovirus (RV). Nucleic acids are isolated and purified from nasopharyngeal (NP) swab specimens obtained from individuals exhibiting signs and symptoms of a respiratory tract infection.

This assay is intended to aid in the differential diagnosis of Adenovirus, human Metapneumovirus, and Rhinovirus infections in humans. Negative results do not preclude Adenovirus, human Metapneumovirus, and Rhinovirus infections and should not be used as the sole basis for treatment or other management decisions. This assay is designed for use on the Panther Fusion system.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device includes software algorithm changes intended to resolve fault modes in the predicate device. Implementation of these changes will improve hMPV specificity (decrease the number of false positives) without significantly changing the clinical results or assay claims. The indications for use of the subject device are the same as those of the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device and predicate device share the same technological characteristics, including the method of detection, intended use, specimen type, components, ancillaries, reagent formulation, packaging, principles of operation, and instrument platform.

The difference between the two devices is the software utilized to run the assay. The subject device will be cleared with system software version 7.2.7 and assay software version 2.3.5.4, including algorithm changes to address false positive hMPV results in the presence of high RV true positive results.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

All analytical and clinical data used to support the predicate device intended use and performance was re-analyzed with the updated software. All pre-determined acceptance criteria from the original protocols were met. The conclusions drawn from the nonclinical and clinical studies demonstrate that the Panther Fusion AdV/hMPV/RV assay on the Panther Fusion system is as safe and effective, and performs comparably to the predicate device currently marketed for the same intended use.