April 22, 2019

InDevR, Inc.
Erica Dawson
Chief Technical Officer
2100 Central Avenue, Suite 106
Boulder, Colorado 80301

Re: K182513
Trade/Device Name: FluChip-8G Influenza A+B Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: Class II
Product Code: OZE, NSU, OEP, OQW
Dated: September 11, 2018
Received: September 12, 2018

Dear Erica Dawson:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182513

Device Name
FluChip-8G Influenza A+B Assay

Indications for Use *(Describe)*
The FluChip-8G Influenza A+B Assay is a multiplex RT-PCR in vitro diagnostic test intended for the qualitative detection and differentiation of seasonal influenza A/H3N2, seasonal influenza A/H1N1pdm09, and "non-seasonal" influenza A subtypes other than seasonal H1N1pdm09 or H3N2. The assay is also intended for the qualitative detection and differentiation of the genetic lineage of human influenza B viruses as B/Victoria or B/Yamagata. The assay is designed for use on influenza nucleic acids isolated and purified from nasopharyngeal swab and nasal swab specimens from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors.

This assay amplifies the hemagglutinin (HA) gene segment, neuraminidase (NA) gene segment, matrix (M) gene segment, non-structural (NS) gene segment, and nucleoprotein (NP) gene segment for detection and discrimination of influenza A, and amplifies the hemagglutinin (HA) gene segment and neuraminidase (NA) gene segment for detection and discrimination of influenza B. This assay is not intended to detect influenza C viruses.

FluChip-8G Influenza A+B Assay "non-seasonal" influenza A positive results are for the presumptive detection of influenza A subtypes other than seasonal influenza A/H1N1pdm09 or A/H3N2. The definitive identification of a "non-seasonal" influenza A case requires additional testing and confirmation procedures in consultation with the appropriate public health authorities (e.g., local or state public health departments, etc.) for whom reporting is necessary.

Negative results do not preclude influenza virus infection. FluChip-8G Influenza A+B Assay "non-seasonal" influenza A negative results, even in the context of a FluChip-8G Influenza A+B Assay positive result for seasonal influenza A/H1N1pdm09 or A/H3N2, or influenza B, do not preclude "non-seasonal" influenza A infection and should not be used as the sole basis for patient management decisions.

Performance characteristics of the FluChip-8G Influenza A+B Assay for detecting and differentiating seasonal influenza A viruses were established when seasonal influenza A/H3N2 was the predominant influenza A virus circulating in the United States. Performance characteristics may vary with other emerging seasonal influenza A viruses. Performance characteristics of the FluChip-8G Influenza A+B Assay for detecting and differentiating human influenza B genetic lineages were established when influenza B/Victoria was the predominant influenza B virus circulating in the United States.

Due to low prevalence of "non-seasonal" influenza A viruses, performance characteristics of the FluChip-8G Influenza A +B Assay for detecting "non-seasonal" influenza A viruses and distinguishing "non-seasonal" influenza A from seasonal influenza A H1N1pdm09 and H3N2 were assessed exclusively by conducting cross-validation on a total of 759 microarray images generated from bench testing contrived samples consisting of 352 unique "non-seasonal" influenza A strains representing 62 subtypes, and by bench testing contrived samples and surrogate clinical specimens consisting of 133 unique non-seasonal influenza A strains representing 46 subtypes. FluChip-8G Influenza A+B Assay performance may vary when testing "non-seasonal" influenza A strains not represented in the performance assessment.

If infection with a novel influenza A virus strain is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to local or state health department(s) for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens.

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.

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