Date: March 3, 2023

Quidel Corporation
Selena Liu
Senior Regulatory Specialist
10165 McKellar Court
San Diego, California 92121

Re: K230236
Trade/Device Name: Lyra 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, OOI
Dated: January 27, 2023
Received: January 30, 2023

Dear Selena 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 (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,

Himani Bisht -S

Himani Bisht, Ph.D.
Assistant Director
Viral Respiratory and HPV Branch
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OHT7: Office of In Vitro Diagnostics and Radiological health
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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.

510(k) Number *(if known)*
K230236

Device Name
Lyra Influenza A+B Assay

Indications for Use *(Describe)*
The Lyra Influenza A+B Assay is a multiplex Real Time RT-PCR assay for the in vitro qualitative detection and differentiation of influenza A and influenza B viral RNA in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of influenza A and influenza B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay does not detect the presence of influenza C virus.
Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.
Performance characteristics for influenza A were established during the 2011 and 2013 influenza seasons when influenza A/H3 and 2009 H1N1 influenza were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.
If infection with a novel influenza A virus 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 state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
The assay can be performed using either the Life Technologies QuantStudio Dx, the Applied Biosystems 7500 Fast Dx or the Cepheid SmartCycler II.

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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510(K) SUMMARY

Submitter
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Date Prepared
Jan 27, 2023

Proprietary and Established Names
Lyra Influenza A+B Assay

Common Name
Lyra Influenza A+B Assay

Classification

Product Code	Classification	Panel	Regulatory Section	Description
OZE	II	Microbiology	21 CFR 866.3980	Influenza A And Influenza B Multiplex Nucleic Acid Assay
OOI	II	Clinical Chemistry	21 CFR 862.2570	Real Time Nucleic Acid Amplification System

Predicate Device
K131728

Device Description
The Lyra Influenza A+B Assay detects viral RNA that have been extracted from a patient sample using the NucliSENS easyMAG or EMAG automated extraction platform. A multiplex RT-PCR is carried out under optimized conditions in a single tube generating amplicons for each of the target viruses present in the sample. This reaction is performed utilizing either the Life Technologies QuantStudio™ Dx, the Applied Biosystems® 7500 Fast Dx, or the Cepheid® SmartCycler® II. Identification of influenza A occurs by the use of target specific primers and a fluorescent-labeled probe that hybridizes to a conserved influenza A sequence within the matrix protein gene. Identification of influenza B occurs by the use of target specific primers and fluorescent-labeled probes that will hybridize to a conserved influenza B sequence within the neuraminidase gene.

Intended Use

The Lyra Influenza A+B Assay is a multiplex Real Time RT-PCR assay for the in vitro qualitative detection and differentiation of influenza A and influenza B viral RNA in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of influenza A and influenza B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay does not detect the presence of influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2011 and 2013 influenza seasons when influenza A/H3 and 2009 H1N1 influenza were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus 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 state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

The assay can be performed using either the Life Technologies QuantStudio™ Dx, the Applied Biosystems® 7500 Fast Dx, or the Cepheid® SmartCycler® II.

Comparison with Predicate

The Lyra Influenza A+B Assay was modified to include a validated nucleic acid extraction platform, BioMerieux NucliSENS EMAG. The predicate device was cleared under K131728 for use with the BioMerieux NucliSENS easyMAG extraction platform. The purpose of the change is to allow customers to continue to use Lyra Influenza A+B Assay after easyMAG is discontinued.

A comparison of the similarities and differences between the devices is provided in the following table.

Features	Predicate Device / Unmodified Device Lyra Influenza A+B Assay (K131728)	Modified Device Lyra Influenza A+B Assay
Intended Use	The Lyra Influenza A+B Assay is a multiplex Real Time RT-PCR assay for the in vitro qualitative detection and differentiation of influenza A and influenza B viral RNA in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of influenza A and influenza B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay does not detect the presence of influenza C virus. Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2011 and 2013 influenza seasons when influenza A/H3 and 2009 H1N1 influenza were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus 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 state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens. The assay can be performed using either the Life Technologies QuantStudio™ Dx, the Applied Biosystems® 7500 Fast Dx, or the Cepheid® SmartCycler® II.	Same
Test Principle	Multiplex RT-PCR	Same
Detection Method	Multiplex assay using different reporter dyes for each target	Same
Assay Result	Qualitative	Same
Analyte	Influenza A virus, influenza B virus	Same
Specimen Type	Nasal swab and nasopharyngeal swab	Same
Extraction Method	BioMerieux NucliSENS easyMAG	BioMerieux NucliSENS easyMAG and EMAG
Quality Control	Process Control (PRC)	Same

Summary of Performance Data

Non-clinical and clinical verification and validation activities conducted with the Lyra Influenza A+B Assay demonstrate that the modified device met predetermined acceptance criteria, supporting equivalency of the modified device to the cleared device. All verification and validation activities were performed in accordance with relevant standards, established plans, protocols, and Design Control procedures. Testing verified all acceptance criteria were met. Verification of the changes did not raise any new items of safety and effectiveness. Evidence is demonstrated through the following studies:

- Limit of Detection Equivalency Study
- Clinical Equivalency Study

Conclusion

These studies demonstrated equivalent performance of the Lyra Influenza A+B Assay to the predicate product K131728.