Date: March 10, 2023

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

Re: K230349
Trade/Device Name: Lyra RSV + hMPV Assay
Regulation Number: 21 CFR 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OEM, OCC
Dated: February 8, 2023
Received: February 9, 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,

Joseph Briggs -S

Joseph Briggs, Ph.D.
Deputy Branch Chief
Viral Respiratory and HPV Branch
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.

510(k) Number *(if known)*
K230349

Device Name
Lyra RSV + hMPV Assay

Indications for Use *(Describe)*
The Lyra RSV + hMPV Assay is a multiplex Real-Time PCR (RT-PCR) assay for the qualitative detection and identification of respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) ribonucleic acid (RNA) extracted from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. This in vitro diagnostic test is intended to aid in the differential diagnosis of RSV and hMPV infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV.
Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.
Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection.
The Lyra RSV + hMPV Assay can be performed using either the Life Technologies QuantStudio Dx RT-PCR Instrument, the Applied Biosystems 7500 Fast Dx RT-PCR Instrument, or the Cepheid SmartCycler II 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

Submitter
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Submission Contact
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Date Prepared
Feb 08, 2023

Proprietary and Established Names
Lyra RSV + hMPV Assay

Common Name
Lyra RSV + hMPV Assay

Classification

Product Code	Classification	Regulatory Section	Description
OEM, OCC	II	21 CFR 866.3980	Respiratory Viral panel multiplex nucleic acid assay

Panel
Microbiology

Predicate Device
K131813

Device Description
The Lyra RSV + hMPV Assay detects viral nucleic acids that have been extracted from a patient sample using the NucliSENS® easyMAG® or NucliSENS® EMAG® automated extraction platform. A multiplex RT-PCR reaction is then performed in a single tube generating amplicons for each of the target viruses present in the sample. This reaction is performed utilizing either the Cepheid SmartCycler® II, the Applied Biosystems 7500 Fast DX, or the Life Technologies QuantStudio™ Dx. Identification of RSV and hMPV and the PRC occurs by the use of target-specific primers and fluorescent-labeled probes that hybridize to conserved regions in the genomes of RSV and hMPV and the PRC.

Intended Use
The Lyra RSV + hMPV Assay is a multiplex Real-Time PCR (RT-PCR) assay for the qualitative detection and identification of respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) ribonucleic acid (RNA) extracted from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. This in vitro diagnostic test is intended to aid in the differential diagnosis of RSV and hMPV infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four

genetic sub-lineages of hMPV.

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

Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection.

The Lyra RSV + hMPV Assay can be performed using either the Life Technologies QuantStudio Dx RT-PCR Instrument, the Applied Biosystems 7500 Fast Dx RT-PCR Instrument, or the Cepheid SmartCycler II System.

Comparison with Predicate

The Lyra RSV+hMPV Assay was modified to include a validated nucleic acid extraction platform, BioMerieux NucliSENS EMAG. The predicate device was cleared under K131813 for use with the BioMerieus NucliSENS easyMAG extraction platform. The purpose of the change is to allow customers to continue to use Lyra RSV+hMPV 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 Quidel RSV+hMPV Assay (K131813)	Modified Device Lyra RSV + hMPV Assay
Intended Use	The Quidel Molecular RSV + hMPV Assay is a multiplex Real-Time PCR (RT-PCR) assay for the qualitative detection and identification of respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) ribonucleic acid (RNA) extracted from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. This in vitro diagnostic test is intended to aid in the differential diagnosis of RSV and hMPV infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV. Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection. The Quidel Molecular RSV + hMPV Assay can be performed using either the Life Technologies QuantStudio Dx RT-PCR Instrument, the Applied Biosystems 7500 Fast Dx RT-PCR Instrument, or the Cepheid SmartCycler II System.	Same*
Test Principle	Multiplex RT-PCR	Same
Detection Method	Multiplex assay using different reporter dyes for each target	Same
Assay Result	Qualitative	Same
Analyte	RSV and hMPV	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
*The predicate device name was changed from Quidel Molecular RSV + hMPV Assay to Lyra RSV + hMPV Assay in CR210354.		

Summary of Performance Data

Non-clinical and clinical verification and validation activities conducted with the Lyra RSV+hMPV 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 Equivalence Study

Conclusion

These studies demonstrated equivalent performance of the Lyra RSV+hMPV Assay to the predicate product K131813.