



November 28, 2023

Cue Health Inc.
Sharon Young
Senior Manager, Regulatory Affairs
4980 Carroll Canyon Road, Suite 100
San Diego, California 92121

Re: K232643

Trade/Device Name: Cue COVID-19 Molecular Test
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-the-counter test to detect SARS-CoV-2 from clinical specimens
Regulatory Class: Class II
Product Code: QWB
Dated: August 29, 2023

Received: August 30, 2023

Dear Sharon Young:

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. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Division of Microbiology Devices

OHT7: Office of In Vitro Diagnostics
and Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K232643

Device Name
Cue COVID-19 Molecular Test

Indications for Use (Describe)

The Cue COVID-19 Molecular Test is a nucleic acid amplification assay that is used with the Cue Health Monitoring System (Cue Cartridge Reader) for the rapid, qualitative detection of SARS-CoV-2 nucleic acid directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 (i.e., symptomatic).

A negative test result is presumptive, and it is recommended these results be confirmed by a lab-based molecular SARS-CoV-2 assay if necessary for patient management. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision.

This test is intended to be sold over-the-counter (OTC) for testing of individuals 18 years of age and older.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



Applicant: Cue Health Inc.
4980 Carroll Canyon Road, Suite 100
San Diego, CA. 92121

Establishment Registration Number: 10084596

Contact Person: Sharon Young
Senior Manager, Regulatory Affairs
s.young@cue.me

Proprietary Name: Cue COVID-19 Molecular Test

US Product Code: QWB

US Product Name: Over-the-counter molecular test to detect SARS-CoV-2 from clinical specimens

US Regulation Number: 21 CFR § 866.3984

Classification: Class II (Special Controls)

Predicate Device: Cue COVID-19 Molecular Test (DEN220028)

Intended Use

The Cue COVID-19 Molecular Test is a nucleic acid amplification assay that is used with the Cue Health Monitoring System (Cue Cartridge Reader) for the rapid, qualitative detection of SARS-CoV-2 nucleic acid directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 (i.e., symptomatic).

A negative test result is presumptive, and it is recommended these results be confirmed by a lab-based molecular SARS-CoV-2 assay if necessary for patient management. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment.



Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision.

This test is intended to be sold over-the-counter (OTC) for testing of individuals 18 years of age and older.

Device Description

The Cue Health Monitoring System: The Cue Health Monitoring System consists of the Cue Cartridge Reader, charging cable and power adapter. The Cue Cartridge Reader is an automated analyzer for use with Cue cartridges and the Cue Health App installed on a mobile smart device (e.g., Apple® iPhone®, Android™) to perform *in vitro* diagnostic testing. The Cue system is designed to be an easy-to-use, portable testing device for use at home and in point-of-care CLIA Waived settings. Cue cartridges contain the reagents and associated materials required for sample testing which occurs inside the cartridge. Sample analysis takes place within the Cue Cartridge Reader and the test result is wirelessly sent to the user's mobile smart device. The Cue test result is displayed to the user in the Cue Health App installed on a compatible mobile smart device. The main steps for using the Cue Cartridge Reader with the Cue COVID-19 Molecular Test Cartridge are: (1) install the Cue Health App on a compatible mobile smart device and register for a Cue Health App account; (2) connect the mobile smart device with the Cue Cartridge Reader (this allows for the test result to be sent to the particular mobile smart device); (3) insert the Cue COVID-19 Molecular Test Cartridge into the Cue Cartridge Reader; (4) collect a nasal sample using the Cue Sample Wand; and (5) insert the Cue Sample Wand with nasal sample into the Cue COVID-19 Molecular Test Cartridge. Testing starts automatically once the Cue Sample Wand is inserted into the cartridge and proceeds



without intervention from the user. When the test is completed, the Cue test result is automatically sent to the user's mobile smart device via BLUETOOTH® technology and displayed to the user in the Cue Health App installed on the mobile smart device.

The Cue Sample Wand: The Cue Sample Wand is a single-use, sterile, disposable swab used for collection of a nasal swab sample from the anterior of the human nose. The Wand is comprised of a plastic wand handle and flocked tip. The flock fiber material, fiber adhesive, and handle have been tested for biocompatibility.

The Cue COVID-19 Molecular Test Cartridge: The Cue COVID-19 Molecular Test Cartridge contains the reagents and associated materials required for detection of COVID-19 in nasal samples collected using the Cue Sample Wand. Each cartridge contains an internal control that controls for the process steps of the Cue test (e.g., sample collection, pellet mixing, amplification). Testing takes place within the cartridge. Testing duration is approximately 20 minutes from Sample Wand insertion to results.

The Cue COVID-19 Molecular Test Cartridge and the sterile Cue Sample Wand are packaged together; both are single-use only.

The Cue Health App: The Cue Cartridge Reader interfaces with the user through the Cue Health App installed on the user's mobile smart device. The Cue Health App enables the user to create a Cue Health App account and connect the mobile smart device to the Cue Cartridge Reader. The Cue Health App also provides the user with the precautions and limitations of the Cue COVID-19 Molecular Test, video tutorials for sample collection and running the test, and is the primary display of the test results.

Comparison to Predicate

Tables 1 and 2 show the similarities and differences for the predicate and candidate devices.



Table 1: Similarities of the Predicate Device and Candidate Device

	Predicate Device	Candidate Device
Name	Cue COVID-19 Molecular Test	Cue COVID-19 Molecular Test
FDA Cleared Product File Number	DEN220028	
Product Code and Regulation Number	QWB 21 CFR § 866.3984	Same
Intended Use	<p>The Cue COVID-19 Molecular Test is a nucleic acid amplification assay that is used with the Cue Health Monitoring System (Cue Cartridge Reader) for the rapid, qualitative detection of SARS-CoV-2 nucleic acid directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 (i.e., symptomatic).</p> <p>A negative test result is presumptive, and it is recommended these results be confirmed by a lab-based molecular SARS-CoV-2 assay if necessary for patient management. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment.</p> <p>Positive results do not rule out co-infection with other respiratory pathogens.</p> <p>This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision.</p>	Same



	Predicate Device	Candidate Device
Name	Cue COVID-19 Molecular Test	Cue COVID-19 Molecular Test
	This test is intended to be sold over-the-counter (OTC) for testing of individuals 18 years of age and older.	
Target	SARS-CoV-2	Same
Technology	Isothermal nucleic acid amplification	Same
Instrument	Cue Health Monitoring System and Cue Health App	Same
Sample Type	Anterior nasal swab specimens	Same
Sample Extraction prior to assay	No	Same
Performance	Established in DEN220028	Same

Table 2: Differences between the Predicate Device and Candidate Device

	Predicate Device	Candidate Device
Name	Cue COVID-19 Molecular Test	Cue COVID-19 Molecular Test
Stability Claims	59°F (15°C) - 72°F (22°C)	59°F (15°C) - 86°F (30°C)

Performance Testing

A multi-lot reagent stability study was conducted to establish the shelf-life of the Cue COVID-19 Molecular Test cartridge. Cartridges were stored at 15°C and 30°C. Three different lots were tested monthly. Cartridge stability was evaluated by the agreement with the negative or positive results expected for the testing panel.



Conclusion

The real-time stability study results support expiration dating of up to three months after manufacture. The current device demonstrates substantial equivalence to the predicate device, as granted De Novo classification through DEN220028.