510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K232643

B Applicant

Cue Health Inc.

C Proprietary and Established Names

Cue COVID-19 Molecular Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QWB	Class II	21 CFR 866.3984 - Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

The purpose of this submission is to expand the Cue COVID-19 Molecular Test cartridge shelf temperature claim from 15℃ - 22℃ to 15℃ - 30℃.

B Measurand:

SARS-Coronavirus 2 (SARS-CoV-2) nucleic acid

C Type of Test:

Isothermal nucleic acid amplification test

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

A mobile smart device with wifi access and the Cue Health Monitoring System (Cue Reader).

IV Device/System Characteristics:

A Device Description:

The device consists of the Cue Health Monitoring System (Cue Reader), the Cue COVID-19 Molecular Test Cartridge, and the Cue sample wand. Users must first download and install the Cue Health App onto their mobile smart device. Users then create an account (first time use) and pair the Cue Reader with the mobile smart device. Multiple profiles can be set up under each user account. The appropriate profile is selected and the user inserts the Cue COVID-19 Molecular Test Cartridge into the Cue Reader. The Cue COVID-19 Molecular Test Cartridge must warm up prior to initiating a run. The user collects an anterior nasal swab sample by swabbing both nares with the Cue sample wand and then inserts the Cue sample wand nasal sample into the port of the Cue COVID-19 Molecular Test Cartridge. The test will start as soon as the Cue Sample Wand is inserted into the Cue COVID-19 Molecular Test Cartridge and is completed in 20 minutes. The Cue Health App will show the Cue COVID-19 Molecular Test result when the test is complete. The result is saved in the Cue Account profile that was selected before the test started.

B Principle of Operation:

The Cue COVID-19 Molecular Test Cartridge utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 nucleic acids. This test is a molecular nucleic acid amplification test (NAAT) that detects the nucleic acid of SARS-CoV-2 using a molecular amplification reaction. The SARS-CoV-2 target primers amplify a region of the nucleocapsid (N) gene. The SARS-CoV-2 target forward primer is conjugated to an affinity tag. RNase P serves as the internal control. The RNase P forward primer is conjugated to a different affinity tag. Both SARS-CoV-2 target and RNase P reverse primers are conjugated to an enzyme. Both the SARS-CoV-2 target and RNase P probes bind to the middle-region of the target amplicon. Following target amplification, the amplicons are bound to a functionalized electrode (one for SARS-CoV-2 and one fore RNase P) via the affinity tag conjugated to the forward primer. The enzyme bound to the reverse primer then catalyzes a redox reaction. The current flow from the electrodes provides a nanoampere signal that is converted to a positive or negative result (based on a pre-determined cutoff).

The RNase P internal control has been designed to control for presence of human cellular material in the sample and proper assay execution including sample lysis, inhibition, amplification, and assay reagent function for each critical step. If RNase P is not detected, the Cue COVID-19 Molecular Test will return an "Invalid" result.

When the user inserts the Cue sample wand with anterior nasal sample into the cartridge, the test automatically begins. Heating, mixing, amplification, and detection take place within the cartridge.

C Instrument Description Information:

1. Instrument Name:
   Cue Health Monitoring System (Cue Reader).

2. Specimen Identification:
   Anterior Nasal Swabs.

3. Specimen Sampling and Handling:
   Once the sample has been collected, the Cue sample wand is immediately inserted directly into the Cue COVID-19 Molecular Test Cartridge.

4. Calibration:
   Not Applicable.

5. Quality Control:
   Internal Control.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Cue COVID-19 Molecular Test

B Predicate 510(k) Number(s):
DEN220028

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232643	DEN220028
Device Trade Name	Cue COVID-19 Molecular Test	Same
General Device Characteristic Similarities		
Intended Use/Indications For 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	Same

	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.	
Target	SARS-CoV-2 RNA	Same
Technology	Isothermal nucleic acid amplification	Same
Instrument	Cue Health Monitoring System and Cue Health App	Same
Sample Type	Anterior Nasal Swabs	Same
General Device Characteristic Differences		
Cartridge Storage Temperature	15°C - 22°C	15°C - 30°C

VI Standards/Guidance Documents Referenced:

Document Number	Title	Publishing Organization
EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline	CLSI

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Please see decision summary for DEN220028.

2. Linearity:
   This study is not applicable as this test device is a qualitative assay.

3. Analytical Specificity/Interference:
   Please see decision summary for DEN220028.

4. Assay Reportable Range:
   This section is not applicable as this test device is a qualitative assay.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   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 at monthly intervals. Cartridge stability was evaluated by the agreement with the negative or positive results expected for the testing panel. The testing panel consisted of negative clinical nasal matrix spiked onto Cue sample wands or inactivated SARS-CoV-2 diluted into clinical nasal matrix to 3xLoD and then spiked onto Cue sample wands. Ten negative and 10 positive Cue sample wands were tested for each lot at each storage temperature and duration. The acceptance criteria were 100% agreement with the expected results for the positive and negative panel member.

If the acceptance criteria were not met at two sequential timepoints, then the study for that lot was stopped. The overall passing stability was determined using earliest of the reagent stability results for the three lots tested. The overall stability claim was supported by acceptable data that is approximately 10% longer than the claimed expiration dating.

The study results support expiration dating of up to three months after manufacture when stored at 15℃ to 30℃.

6. Detection Limit:
   Please see decision summary for DEN220028.

7. Assay Cut-Off:
   Please see decision summary for DEN220028.

8. Accuracy (Instrument):
   Please see decision summary for DEN220028.

9. Carry-Over:
   Please see decision summary for DEN220028.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   No method comparison was included as the device design is identical to the predicate.

2. Matrix Comparison:
   Not Applicable.

C Clinical Studies:
Please see decision summary for DEN220028.

D Clinical Cut-Off:
There is no clinical cutoff related to the presence of SARS-CoV-2 in patient samples. This section is therefore not applicable.

E Expected Values/Reference Range:
Please see decision summary for DEN220028.

F Other Supportive Instrument Performance Characteristics Data:
Please see decision summary for DEN220028 for Usability and User Comprehension testing; Hazard Analysis; description of Fail Safes; and Flex Studies.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.