April 3, 2023

Mawi DNA Technologies
Bassam El-Fahmawi
President
26203 Production Avenue, Suite 3
Hayward, California 94545

Re: K221802
Trade/Device Name: iSWAB-Respiratory Tract Sample Collection Media-Extraction Less (iSWAB-RC-EL)
Regulation Number: 21 CFR 866.2950
Regulation Name: Microbial Nucleic Acid Storage And Stabilization Device
Regulatory Class: Class II
Product Code: QBD
Dated: June 20, 2022
Received: June 21, 2022

Dear Bassam El-Fahmawi:

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,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Branch Chief
Bacterial Respiratory and Medical Countermeasures 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)*
K221802

Device Name
iSWAB-Respiratory Tract Sample Collection Media-Extraction Less (iSWAB-RC-EL)

Indications for Use *(Describe)*

The iSWAB-Respiratory Tract Sample Collection Media-Extraction Less collection device is intended for the stabilization and inactivation of upper respiratory and saliva human specimens suspected of containing SARS-CoV-2. This device can be used for the collection, transport, and storage of specimens at ambient temperature. Specimens collected in the iSWAB-Respiratory Tract Sample Collection Media-Extraction Less collection device are suitable for use with legally marketed molecular diagnostic tests.

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.

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## 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

## I. SUBMITTER

Mawi DNA Technologies LLC 2603
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Contact Person: Dr. Bassam El-Fahmawi, PhD

Date Prepared: June 17, 2022

## II. DEVICE

| | |
|---|---|
| Device Trade Name: | **(iSWAB™-RC-EL)** |
| | **iSWAB™-R**espiratory Tract Sample **C**ollection Media-**E**xtraction **L**ess |
| Classification Name: | Microbial Nucleic Acid Storage and Stabilization Device |
| Regulation: | 21 CFR §866.2950 |
| Regulatory Class: | Class II |
| Device Panel: | Microbiology |
| Product Classification Code: | QBD |

For invitro diagnostic use only: Rx only

## III. PREDICATE DEVICE

| | |
|---|---|
| Predicate Manufacturer: | Zymo Research |
| Predicate Trade Name: | DNA/RNA Shield Collection Tube |
| Predicate 510(k): | K202641 |

No reference devices were used in this submission.

## IV. DEVICE DESCRIPTION

**General Description**:

The **iSWAB™-Respiratory Tract Sample Collection Media-Extraction Less (iSWAB™-RC-EL)** collection device consists of a collection tube that is pre-filled with 800 µL of the **iSWAB™-RC-EL** non-toxic, stabilizing buffer and fitted with a proprietary insert. The insert is designed to optimize the release of specimens collected with swabs into the stabilizing buffer, creating a minimal footprint and allowing for swab-free transport of specimens. The **iSWAB™-RC-EL** collection device eliminates the costly and time-consuming RNA isolation step from diagnostic workflows.

## V. INDICATIONS FOR USE

The **iSWAB-Respiratory Tract Sample Collection Media-Extraction Less** collection device is intended for the stabilization and inactivation of upper respiratory and saliva human specimens suspected of containing SARS-CoV-2. This device can be used for the collection, transport, and storage of specimens at ambient temperature. Specimens collected in the **iSWAB-Respiratory Tract Sample Collection Media-Extraction Less** collection device are suitable for use with legally marketed molecular diagnostic tests.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

| Feature | Subject Device | Predicate Device (K202641) |
|---|---|---|
| **Indications for Use** | The **iSWAB-Respiratory Tract Sample Collection Media-Extraction Less** collection device is intended for the stabilization and inactivation of upper respiratory and saliva human specimens suspected of containing SARS-CoV-2. This device can be used for the collection, transport, and storage of specimens at ambient temperature. Specimens collected in the **iSWAB-Respiratory Tract Sample Collection Media-Extraction Less** collection device are suitable for use with legally marketed molecular diagnostic tests. | The DNA/RNA Shield™ collection tube is intended for the stabilization and inactivation of upper and lower respiratory human specimens suspected of containing SARS-CoV- 2.<br>These devices can be used for collection transport and storage of specimens at ambient temperatures (20- 25°C).<br>Specimens collected and stored in a DNA/RNA Shield™ collection tube are suitable for use with legally marketed molecular diagnostic tests. |
| **Inactivation** | SARS-CoV-2 inactivation | SARS-CoV-2 inactivation |
| **Storage** | SARS-CoV-2: 28 days for nasal specimens and 33 days for saliva at 15-30ºC | SARS-CoV-2 RNA: 28 Days at 20-25ºC |
| **Sample source** | Human respiratory | Human respiratory |
| **Sample Stability at 2-4ºC** | No 2-4ºC claim | No 2-4ºC claim |
| **Analyte** | RNA from SARS-CoV-2 | RNA from SARS-CoV-2 |
| **Specimen Type** | Nasal and Saliva Specimens for SARS-CoV-2 | Lower, Upper Respiratory and Saliva Specimens for SARS-CoV-2 |
| **Sample Processing Steps** | RNA extraction optional | Requires RNA extraction before use |
| **Device Specs** | 12X50 mm Screwcap vial, with patented insert, pre-filled with **iSWAB™-Respiratory Tract Sample Collection Media-Extraction Less** stabilizing buffer (800µL) | 12X80 mm Screwcap vial pre-filled with DNA/RNA Shield (1 mL or 2 mL) |
| **Shelf-Life** | 15 months | 24 months |

## VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

| Test | Subject Device | Predicate Device [K202641] |
|---|---|---|
| **Inactivation** | An inactivation study was conducted to demonstrate inactivation of the SARS-CoV-2 virus. | An inactivation study was conducted to verify that DNA/RNA Shield inactivates SARS-CoV-2 virus. |
| **Limit of Detection** | An analytical sensitivity study was conducted to determine the Limit of Detection of SARS-CoV-2 collected in **iSWAB™-Respiratory Tract Sample Collection Media-Extraction Less** in combination with the BGI Real-Time Fluorescent RT-PCR Kit for Detecting SARS- CoV-2. | An analytical sensitivity study was conducted to determine the SARS- CoV-2 Limit of Detection (LoD) obtained by DNA/RNA Shield in combination with the *Quick* SARS- CoV-2 rRT-PCR Kit. |
| **Specimen Stability** | A stability study was conducted to demonstrate that SARS-CoV-2 is stabilized long-term at ambient temperature in **iSWAB™-RC-EL.** | A stability study was designed to demonstrate that SARS-CoV-2 RNA from sputum and oral swab was preserved and stabilized in DNA/RNA Shield media. |
| **Precision/ Reproducibility** | Two reproducibility studies were conducted to evaluate:<br>- Lot-Lot reproducibility,<br>- Day-Day, and<br>- Operator-Operator Reproducibility.<br>The results of this study demonstrated lot-lot reproducibility. | N/A – not available in Decision Summary |
| **Compatibility** | Samples collected with **iSWAB™- RC-EL** (no RNA extraction steps required) are directly compatible with the CDC 2019-Novel Coronavirus (2019-nCoV) RT-PCR Diagnostic Panel (with TaqPath 1-Step Multiplex Master Mix, the BGI Real- Time Fluorescent RT-PCR Kit, Bio- Rad's Reliance SARS-CoV-2 RT- PCR Assay, the PRIME CovidDetect RT-LAMP-based assay, and the UCSD RT-LAMP and LFIA test for the detection of SARS-CoV-2.<br>Compatibility is not limited to these assays. | N/A – Not available in Decision Summary |

**Sterilization & Shelf-life Testing**

This device is non-sterile.

The shelf life for the **iSWAB-Respiratory Tract Sample Collection Media-Extraction Less** Collection tube with media is 15 months after the date of manufacture. The stability of the **iSWAB-Respiratory Tract Sample Collection Media-Extraction Less** Collection tube with media was performed using Realtime and Accelerated stability on a total of 3 lots. Stability looked for bacterial and fungal growth in the media along with properties of the media, appearance, pH, voltage resistance and density.

**Biocompatibility Testing**

Not Applicable -IVD, no patient contact

**Electrical safety and electromagnetic compatibility (EMC)**

Not Applicable (Passive Device)

**Software Verification and Validation Testing**

Not Applicable (Passive Device)

**Mechanical and acoustic Testing**

Not Applicable

**Animal Study**

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

**Human Clinical Performance Testing**

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

## VIII. CONCLUSIONS

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