MagBio Genomics, Inc.
% Mukesh Kumar
CEO
Brij Strategic Consultations, LLC
20271 Goldenrod Lane, Suite 2020
Germantown, Maryland 20876

July 28, 2022

Re: K212113
Trade/Device Name: MagXtract Collection Tube
Regulation Number: 21 CFR 866.2950
Regulation Name: Microbial nucleic acid storage and stabilization device
Regulatory Class: Class II
Product Code: QBD
Dated: July 5, 2021
Received: July 7, 2021

Dear Mukesh Kumar:

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,

Kristian Roth, Ph.D.
Deputy Director
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)*
K212113

Device Name
MagXtract Collection Tube

Indications for Use *(Describe)*
The MagXtract Collection Tube collection tube is intended for the stabilization, transportation, and direct lysis of infectious unprocessed nasopharyngeal samples suspected of containing SARS-COV-2 virus RNA. These devices can be used for collection transport and storage of specimens at refrigerated (2-8°C) or ambient temperatures (20-25°C). Specimens collected and stored in a MagXtract collection tube are suitable for use with legally marketed molecular diagnostic devices.

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

1. 510(k) Submitter:

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2. Company Contact:

Mothomang Mlalazi-Oyinloye Ph.D.
Associate Scientific Director

3. Date of Submission: May 15, 2021

4. US Agent:

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20271 Goldenrod Lane, Suite 2020
Germantown, MD 20876
Phone: 240-750-4893
Email: mkumar@fdamap.com

5. Device Classification:

| | |
|---|---|
| Trade name: | MagXtract Collection Tube |
| Common name: | Specimen Collection Tube |
| Device: | Collection Tube |
| Regulation: | 870.2950 |
| Class: | 2 |
| Product Code: | QBD |

6. Predicate 1:

| | |
|---|---|
| Applicant: | Longhorn Vaccines and Diagnostics, LLC |
| Device: | PrimeStore MTM |
| 510(k) Number: | DEN170029 |

7. Device Description. The MagXtract collection tube is intended for the collection, transportation, direct lysis, and stabilization of RNA from unprocessed nasopharyngeal swab samples suspected of containing SARS-COV-2.

   The MagXtract collection tube stores and transports specimens in a closed tube. Proper specimen collection and transport are essential in molecular testing and obtaining accurate test results. MagXtract collection tube allows for the stabilization and transportation of nasopharyngeal swab samples at ambient temperature from the collection site to the processing laboratory.

   The MagXtract collection tube consists of a sterile plastic, 5 ml cryogenic collection tube pre-filled with 1.2 mL of proprietary stabilization/lysis buffer (MagBio CTL Medium). MagBio

CTL Medium is intended to disrupt/lyse cells and stabilize SARS-COV-2. The preserved and stabilized RNA maintains its integrity for downstream molecular based detection/analysis. MagXtract collection tube may be used in conjunction with a swab or as a tube alone.

8. Indications For Use. The MagXtract collection tube collection tube is intended for the stabilization, transportation, and direct lysis of infectious unprocessed nasopharyngeal samples suspected of containing SARS-COV-2 virus RNA. These devices can be used for collection transport and storage of specimens at refrigerated (2-8°C) or ambient temperatures (20-25°C). Specimens collected and stored in a MagXtract collection tube are suitable for use with legally marketed molecular diagnostic devices.

Comparison To Predicate… As shown in Table 5, MagXtract PrimeStore MTM.

**Table 5 – Comparison Table**

| **Device & Predicate Device(s):** | Device: K212113 | Predicate: DEN170029 |
|---|---|---|
| Device Trade Name | | |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | The MagXtract collection tube collection tube is intended for the stabilization, transportation, and direct lysis of infectious unprocessed nasopharyngeal samples suspected of containing SARS-COV-2 virus RNA. These devices can be used for collection transport and storage of specimens at refrigerated (2-8°C) or ambient temperatures (20-25°C). Specimens collected and stored in a MagXtract collection tube are suitable for use with legally marketed molecular diagnostic devices. | PrimeStore MTM is intended for the stabilization, transportation and inactivation of infectious unprocessed nasal washes suspected of containing Influenza A virus RNA. PrimeStore MTM is also intended for the stabilization, transportation and inactivation of infectious unprocessed sputum samples suspected of containing *Mycobacterium tuberculosis* DNA from human samples. |
| Inactivation test | Inactivaes virus | same |
| **General Device Characteristic Differences** | | |
| Specimen stability | MagXtract collection tube preserves SARS-CoV-2 RNA for up to 5 days at 2-4°C and 20-25°C | Primestore MTM medium preserves influenza A RNA for up to 8 days at 27°C and 29 days at 4°C |
| Specimen Type | Nasopharyngeal swab suspected of containing SARS-CoV-2. | Nasal wash suspected of containing Influenza A virus. Sputum samples suspected of containing MTB. |

9. **Performance data:**

**Limit of detection**

An analytical sensitivity study was conducted to determine the SARS-CoV-2 Limit of Detection (LoD) obtained using MagXtract collection tubes in combination with TaqPath COVID-19 Combo Kit (detection of SARS-COV-2).

The viral culture lysate of SARS-COV-2 was spiked into MagXtract collection tube containing Magbio CTL Medium with nasopharyngeal swab matrix. RNA was captured from MagXtract Collection Tube using MagBio Genomics paramagnetic beads on KingFisher Flex Purification system.

RNA extracts from Kingfisher Flex system were amplified using SARS-CoV-2 RT-PCR Kit (TaqPath COVID-19 Combo Kit). MagXtract collection tube had LoD of $1x10^1$ $TCID_{50}$/ml for SARS-COV-2.

**Specimen Stability**

A stability study was undertaken to demonstrate that SARS-CoV-2 is preserved and stabilized in the MagXtract Collection Tube. The stability study used nasopharyngeal matrix in transport media and SARS-CoV-2 viral lysate spiked at the limit of detection. The samples were then extracted using the KingFisher Flex Purification system and amplified using the TaqPath COVID-19 Combo Kit. The results of the SARS-CoV-2 RNA stability study confirmed that RNA was stabilized and preserved in MagXtract Collection Tube met the acceptance criteria of +/- 3.0 Ct after 5 days of storage at refrigeration and room temperature.

10. **Substantial Equivalence:**

Based on the above information, MagXtract Collection Tube is substantially equivalent to the FDA cleared predicates (PrimeStore MTM (DEN170029) for the LoD, stabilization/recovery of samples containing SARS-CoV-2. MagXtract collection tube successfully followed the pathway to substantial equivalence in the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" (July 2014). The steps are summarized below:

- The predicate is legally marketed.
- The subject and predicate devices have the same intended use (and indications).
- Technological differences between the subject and primary predicate were evaluated; none of the differences raised different issues of safety and effectiveness.
- The following methods for evaluation of the effects of different characteristics on safety and effectiveness were deemed acceptable—stability, limit of detection.
- Data from these tests demonstrated equivalence and support the indications for use.