May 4, 2022

BioTeke Corporation (WuXi) Co., Ltd
% Kenneth Kleinhenz
Regulatory Affairs Consultant
QSR Consulting
10807 Dakota Ranch Rd.
Santee, California 92071

Re: K211707
Trade/Device Name: BioTeke Sterile Disposable Virus Sampling Kit
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM, LIO
Dated: May 28, 2021
Received: June 3, 2021

Dear Kenneth Kleinhenz:

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,

Maria Garcia, Ph.D.
Assistant Director
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

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)*
K211707

Device Name
Bioteke Sterile Disposable Virus Sampling Swab Kit

Indications for Use *(Describe)*
The BioTeke Sterile Disposable Virus Sampling Kit is intended for the collection and transport of clinical specimens to the laboratory for standard diagnostic / identification techniques. The BioTeke Sterile Disposable Virus Sampling Kit consists of a sterile swab and culture-based media that can be used for respiratory viral diagnostic assays including, Influenza, Respiratory Syncytial Virus (RSV) A and B, Parainfluenza, Adenovirus, and Rhinovirus.

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.***

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**Date:** 29 April 2022

## ADMINISTRATIVE INFORMATION


| | |
|---|---|
| Manufacturer Name: | BioTeke Corporation (WuXi) Co., Ltd 4th Floor, D5, No. 1719 Huishan Avenue, Wuxi City (21474) Jiangsu, China |
| Official Contact: | Kenneth K. Kleinhenz Regulatory Affairs Telephone (619) 244-9573 Kleinhenz64@gmail.com |


## DEVICE NAME

| | |
|---|---|
| Classification Name: | Culture Media, Non-Propagating Transport |
| Trade/Proprietary Name: | BioTeke Sterile Disposable Virus Sampling Swab Kit |

**ESTABLISHMENT REGISTRATION NUMBER:** 3016837106

## DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in (21 CFR 866.2390), Transport Culture Medium devices consist of a semisolid, usually non-nutrient, medium that is intended to maintain the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. These devices are classified as Class I. Culture Media, Non-Propagating Transport have been assigned Product Code JSM.

## INTENDED USE

The BioTeke Sterile Disposable Virus Sampling Kit is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic/identification techniques. The BioTeke Sterile Disposable Virus Sampling Kit consists of a sterile swab and culture-based media that can be used for respiratory viral diagnostic assays including, Influenza, Respiratory Syncytial Virus (RSV) A and B, Parainfluenza, Adenovirus, and Rhinovirus.

## DEVICE DESCRIPTION

### Design Characteristics

The BioTeke Sterile Disposable Virus Sampling Swab Kit is a specimen collection and transport kit designed to collect a throat or nasal sample from the patient (utilizing the provided Specimen Collection Swab) and subsequently transferring the swab containing the patient's microbial sample into the provide 10mL polymer tube containing 3mL of VTM (Virus Transport Media) for purposes of transferring the swab and associated collected microorganisms into a transport container designed to preserve the sample during transport to the laboratory prior to laboratory analysis. The Specimen Collection Swab is designed with a break point (notched area on the shaft) to allow for the top of the VTM tube to close when the inoculated Specimen Collection Swab is placed into the BioTeke VTM tube.

The Bioteke Sterile Disposable Virus Sampling Swab Kit consists of the following: One (1)
Specimen Collection Swab (sterile and individually packaged)
One (1) Virus Transport Media (10mLpolymer tube containing 3mL of sterile VTM)

The Specimen Collection Swab measured 150mm with a breakpoint location (from the tip) at 80mm, a head length at 20mm and a head width of 3mm. The width of the shaft for the Specimen Collection Swab measures 2.5mm. The 10mL polymer tubes are filled with 3mL of Virus Transport Media (VTM) and secured with a leak-proof polymer cap.

### Material Composition

The single use Specimen Collection Swab is constructed of flocked polyester with an acrylonitrile-butadiene-styrene (ABS) shaft.

The 10mL polymer tubes are aseptically filled with 3mL of VTM (Virus Transport Media) that consists of 1X modified Hank's buffered salt solution consisting of the following:

| | |
|---|---|
| NaCl | $MgSO_4.7H_2O$ |
| KCl | $MgCl_2.6H_2O$ |
| $CaCl_2$ | $Na_2HPO_4.12H_2O$ |
| $KH_2PO_4$ | Sodium bicarbonate |
| Glucose | Phenol Red sodium salt |
| Gentamicin | Polymyxin B |

## EQUIVALENCE TO MARKETED PRODUCT

The BioTeke Sterile Disposable Virus Sampling Swab Kit shares indications and design principles with the following predicate devices: Puritan UTM-RT Collection and Transport System (K113249) and the Copan MSwab™ Collection, Preservation and Transport System (K121039); a Class I medical devices that were cleared for marketing in the United States under K113249 and K121039, respectively.

The BioTeke Sterile Disposable Virus Sampling Swab Kit device is substantially equivalent to the Puritan UTM-RT Collection and Transport System (K113249) predicate device in the following respects:

| | **Subject Device** | **Predicate Device** |
|---|---|---|
| Criteria | **BioTeke Sterile Disposable Virus Sampling Swab Kit** | **Puritan UTM-RT Collection and Transport System (K113249)** |
| Intended Use | The BioTeke Sterile Disposable Virus Sampling Kit is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic / identification techniques. The BioTeke Sterile Disposable Virus Sampling Kit consists of a sterile swab and culture-based media that can be used for respiratory viral diagnostic assays including, Influenza, Respiratory Syncytial Virus (RSV) A and B, Parainfluenza, Adenovirus, and Rhinovirus | Puritan UTM -. RT Collection and Transport System is intended for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the testing laboratory. The specimen transported in the Puritan UTM - RT can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasmal culture |
| Individual Contents | 1 sterile individually wrapped specimen collection swab and<br><br>1 polymer tube containing 3 mL viral transport media | 1 sterile individually wrapped specimen collection swab and<br><br>1 viral transport media polymer tube containing 1mL or 3mL universal transport media |
| Swab | Flocked polyester with acrylonitrile-butadiene-styrene (ABS) shaft | Flocked polyester with polystyrene shaft |
| Swab Breakpoint | 80mm | 80mm and 100mm |
| Single Use Components | Yes | Yes |
| Transport Media Volume | 3mL | 1mL or 3mL |
| Contents of Viral Transport Media | Hank's Balanced Salt Solution<br>Gentamicin<br>Polymyxin B<br>Phenol Red Sodium Salt | Hank's Balanced Salt Solution<br>L-Glutamic Acid<br>Bovine Serum Albumin<br>Phenol Red<br>Gelatin Colistin<br>Sucrose<br>Amphotericin B<br>L-Cysteine Vancomycin<br>HEPES |
| Device Classification Name | Culture Media, Non- propagating Transport | Culture Media, Non-propagating Transport |
| Regulation (CFR Section) | 866.2390 | 866.2390 |
| Product Code | JSM | JSM |
| Class | 1 | 1 |

**PERFORMANCE TESTING**

**Non-Clinical Testing**

Performance testing was conducted on BioTeke Sterile Disposable Virus Sampling Swab Kit. Virus recovery testing demonstrated that the BioTeke Sterile Disposable Virus Sampling Swab Kit meets the requirements of CSLI-M40-A2.

Mechanical testing was performed on the BioTeke Sterile Disposable Virus Sampling Swab Kit which determined the BioTeke Sterile Disposable Virus Sampling Swab Kit to be substantially equivalent to the predicate device.

Biocompatibility studies were conducted per ISO 10993-1 to demonstrate safety of the Bioteke Sterile Disposable Virus Sampling Swab Kit material. The biocompatibility studies demonstrated that the Specimen Collection Swab component of the BioTeke Sterile Disposable Virus Sampling Swab Kit materials are safe for its intended use.

**Virus Viability over Time**

The ability of BioTeke Sterile Disposable Virus Sampling Kit to maintain viability of respiratory viruses was assessed by virus culture after storage at room temperature for 0h, 24h, 48h, 72h, and 120h. The results demonstrate that the viruses influenza, RSV A, RSV B, parainfluenza, adenovirus and rhinovirus stored at 23-25°C were maintained within 0.25 log (PFU/mL) of the input concentration of virus for 48 hours as described in the table below.

| **Virus Viability over Time** | | | | |
|---|---|---|---|---|
| **Organism** | **pfu/ ml T=0** | **pfu/ ml T=24** | **pfu/ ml T=48** | **T=48 hours Log reduction** |
| Influenza A | 85.7 | 64.0 | 54.0 | - 0.20 |
| RSV A | 105.0 | 85.3 | 63.3 | - 0.22 |
| RSV B | 106.7 | 84.7 | 64.3 | - 0.22 |
| Parainfluenza | 167.3 | 141.7 | 104.0 | - 0.21 |
| Adenovirus | 194.7 | 163.0 | 117.0 | - 0.22 |
| Rhinovirus | 137.5 | 108.5 | 89 | - 0.21 |

**Conclusion**

Based on the test principle, design and performance characteristics of the device, the BioTeke Sterile Disposable Virus Sampling Kit is substantially equivalent to the predicate.