510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K211707

B Applicant

BioTeke Corporation (WuXi) Co., Ltd

C Proprietary and Established Names

BioTeke Sterile Disposable Virus Sampling Kit

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JSM	Class I, reserved	21 CFR 866.2390 - Transport Culture Medium	MI - Microbiology
LIO	Class I, reserved	21 CFR 866.2900 - Microbiological specimen collection and transport device	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To make a substantial equivalence determination for the BioTeke Sterile Disposable Virus Sampling Kit for collection and transport of clinical respiratory specimens (Influenza, Respiratory Syncytial Virus (RSV) A and B, Parainfluenza, Adenovirus, and Rhinovirus) to the laboratory for standard diagnostic/identification techniques.

B Type of Test:

Transport Culture Medium Device

III Intended Use/Indications for Use:

A Intended Use(s):

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.

B Indication(s) for Use:

NA

C Special Conditions for Use Statement(s):

R_X - For Prescription Use Only

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

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 measures 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.

B Principle of Operation:

The swab is used to collect nasal or throat samples.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Transport Culture Medium Device

B Predicate 510(k) Number(s):
K113249

C Comparison with Predicate(s):

Table 2. Similarities and *Differences* Between Bioteke Sterile Disposable Virus Sampling Swab Kit and Predicate Device

Device & Predicate Device(s):	**Device: K211707**	**Predicate: K113249**
	Bioteke Sterile Disposable Virus Sampling Swab Kit	Puritan UTM-RT Collection and Transport System
General Device Characteristic Similarities		
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, chiamydial, mycoplasmal and ureaplasmal culture.
Assay Type	Culture Media, Non-propagating Transport	Same.
Storage Temp (until used)	5 to 25°C	2 to 25°C
General Device Characteristic Differences		
Contents of Viral Transport Media	Hank's Balanced Salt Solution, Gentamicin, Polymyxin B, Phenol Red, Sodium Salt	Hank's Balanced Salt Solution L-Glutamic Acid, Bovine Serum Albumin, Phenol Red, Gelatin, Colistin, Sucrose, Amphotericin

		B, L-Cysteine, Vancomycin, HEPES
Transport Media Volume	3 mL	1 mL or 3 mL

VI Standards/Guidance Documents Referenced:

CLSI-M40-A2 Quality Control of Microbiological Transport Systems
ISO 10993-1 Biological Evaluation of Medical Devices
ISO 11137-32017 Sterilization of health care products Radiation-Part **3.** Guidance on dosimetric aspects
ISO 11137-1:2018 Sterilization of health care products - Microbiological methods-Part 1: Determination of a population of microorganisms on products
ISO 11137-2:2009 Sterilization of health care products Microbiological methods-Part 2

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Not applicable

2. Linearity:
   Not applicable

3. Analytical Specificity/Interference:
   Not applicable

4. Assay Reportable Range:
   Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   The ability of BioTeke Sterile Disposable Virus Sampling Kit to maintain viability of respiratory viruses was assessed by virus culture after storage at various conditions (time and time). Viruses were diluted in matrix at approximately 3 X the Limit of Detection (LoD) prior to transfer into the VTM. 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

RSV=respiratory syncytial virus

Additional studies demonstrated that specimens containing the viruses noted in the table above maybe stored under the following conditions: up to 7 days at 2-8°C, or up to 14 days at -70°C.

The expiration date of the single-use sterile sampling swab is 12 months when stored at 5-25°C, in the dark.;

6. Detection Limit:
   Not applicable

7. Assay Cut-Off:
   Not applicable

8. Accuracy (Instrument):
   Not applicable

9. Carry-Over:
   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:
   Method comparison is not applicable for a bacterial transport medium. The device itself does not provide a result that can be used in making a clinical decision. Bench testing studies were done to determine the ability of the Bioteke Sterile Disposable Virus Sampling Swab Kit to maintain viability of viruses commonly found as the etiological agents of respiratory infections. The analytical studies showed acceptable maintenance of respiratory viruses for subsequent viral culture studies.

2. Matrix Comparison:
   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:
   Not applicable

2. Clinical Specificity:

Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   Not applicable

D Clinical Cut-Off:
Not applicable

E Expected Values/Reference Range:
Not applicable

F Other Supportive Performance Characteristics Data:
Not applicable

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.