DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 28, 2017

BIOMERIEUX, INC.
JOLYN TENLLADO
DIRECTOR GLOBAL REGULATORY AFFAIRS MICROBIOLOGY
595 ANGLUM RD.
HAZELWOOD MO 63042

Re: K161816
Trade/Device Name: BacT/ALERT® VIRTUO™ Microbial Detection System
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial growth monitor
Regulatory Class: I
Product Code: MDB
Dated: February 21, 2017
Received: February 23, 2017

Dear Ms. Tenllado:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ribhi Shawar -A

For Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Unknown at time of 510(k) Submission

Device Name
BacT/ALERT® VIRTUO(TM) Microbial Detection System

Indications for Use *(Describe)*

BacT/ALERT® VIRTUO(TM) Microbial Detection System is an automated microbial test system capable of incubating, agitating, and continuously monitoring for the detection of aerobic, facultative, and anaerobic microorganism growth from blood and other normally sterile body fluids.

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.

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510(k) SUMMARY

BacT/ALERT® VIRTUO™ Microbial Detection System

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jolyn Tenllado Director, Global Regulatory Affairs Microbiology
Phone Number:	314 -731-8386
Fax Number:	314-731-8689
Date of Preparation:	June 30, 2016

B. Device Name:

Formal/Trade Name:	BacT/ALERT® VIRTUO™ Microbial Detection System
Classification Name:	21 CFR 866.2560, Microbial Growth Monitor
Common Name:	BacT/ALERT® VIRTUO™; VIRTUO™

C. Predicate Device: BacT/ALERT® 3D Microbial Detection System (K903505/A2)

D. 510(k) Summary:

Intended Use:
BacT/ALERT® VIRTUO™ Microbial Detection System is an automated microbial test system capable of incubating, agitating, and continuously monitoring for the detection of aerobic, facultative, and anaerobic microorganism growth from blood and other normally sterile body fluids.

Device Description:
The VIRTUO Instrument is the next generation of the bioMerieux BacT/ALERT Microbial Detection System. This blood culture instrument consists of an incubator, agitation mechanism, robotic apparatus for automated loading and unloading of bottles and a tactile graphical interface. The VIRTUO is used in conjunction with existing, commercialized BacT/ALERT reagent bottles for clinical use (BacT/ALERT SA, SN, FA Plus, FN Plus and PF Plus culture bottles).

bioMérieux, Inc.
595 Anglum Road, Hazelwood, Missouri 63042-2320, USA Phone: 314/731-8500 800/638-4835 Fax: 314/731-8700
http://www.biomerieux-usa.com

The VIRTUO system utilizes a colorimetric sensor and reflected light to monitor the presence and production of carbon dioxide (CO_2) dissolved in the culture medium. If microorganisms are present in the inoculated sample, carbon dioxide is produced as the organisms metabolize the substrates in the culture medium. When growth of the microorganisms produces CO_2, the color of the gas-permeable sensor installed in the bottom of each culture bottle changes from blue-green to yellow. The color change results in an increase of reflectance units monitored by the system. The VIRTUO optically monitors the reflectance of each bottle over time and will store and interpret readings against algorithms, which are embedded in the firmware and/or software.

Table 1: Similarities & Differences Between BacT/ALERT Microbial Detection Systems

	New Device: BacT/ALERT VIRTUO	**Predicate Device: BacT/ALERT 3D**
Similarities		
Intended Use	The BacT/ALERT® VIRTUO™ Microbial Detection System is an automated microbial test system capable of incubating, agitating, and continuously monitoring for the detection of aerobic, facultative, and anaerobic microorganism growth from blood and other normally sterile body fluids. Note: The intial release of the system will not include detection of Mycobacterium species growth from clinical specimens.	The BacT/ALERT® 3D Microbial Detection System is a totally automated test system capable of incubating, agitating, and continuously monitoring aerobic and anaerobic media inoculated with patient specimens suspected of having bacteremia, fungemia, and/or mycobacteremia (Clinical Use)
Reagent	For use with the BacT/ALERT SA, SN, FA Plus, PF Plus and FN Plus culture bottles (Clinical Use)	For use with the BacT/ALERT SA, SN, FA, PF, FN, MP, FA Plus, FN Plus, PF Plus (Clinical Use)
Detection Method for Microbial Growth	Reflectance change of colorimetric sensor over time to measure metabolic reactants	Reflectance change of colorimetric sensor over time to measure metabolic reactants
Incubation & Agitation	Electrically heated forced air convection incubation. Continuous 12.5° from horizontal sinusoidal rocking of reagent & sample @50-60 cycles/minute.	Electrically heated forced air convection incubation. Continuous 12.5° from horizontal sinusoidal rocking of reagent & sample @50-60 cycles/minute.
Colorimetric Optics	LED emitter with 634nm peak wavelength and 17nm bandwidth/photodiode detector. Four point graduated grey scale optical calibration.	LED emitter with 634nm peak wavelength and 17nm bandwidth/photodiode detector. Four point graduated grey scale optical calibration.
Differences		
Detection algorithms	Proprietary algorithms unique for BacT/ALERT VIRTUO	Proprietary algorithms unique for BacT/ALERT 3D
Capacity	108-6912 bottles	240-1440 bottles
Bottle Loading	Automated loading of bottles placed on conveyor (up to 40 at a time) with bottle label scanning, measuring of sample	Customer scans bottle labels and loads the bottle into a bottle cell of an open drawer, one bottle at a time

	volume & loading via robotic arm into open incubator cell with appropriate agitation. Customer can manually load bottles if automation features are not operable	
Remote Customer Access	Internal (customer site) network access	Unavailable

Performance Characteristics:
The BacT/ALERT VIRTUO Microbial Detection System demonstrated substantially equivalent performance when compared with the BacT/ALERT 3D Microbial Detection System. This 510(k) Premarket Notification presents data in support of the BacT/ALERT VIRTUO. External performance evaluations were conducted at eight external clinical sites. The evaluation included testing of blood & sterile body fluids using the BacT/ALERT SA, SN, FA Plus, PF Plus and FN Plus culture bottles with the VIRTUO and 3D Systems.

The following tables compare results of the BacT/ALERT VIRTUO to BacT/ALERT 3D blood cultures for all compliant blood culture bottles that yielded any number of isolates on subculture.

BacT/ALERT FA Plus: Blood – Compliant –Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	64	6.1 (64/1057)	66	6.2 (66/1057)	0.970	0.821, 1.119
Contaminant	7	0.7 (7/1057)	11	1.0 (11/1057)	0.636	
Unknown	2	0.2 (2/1057)	2	0.2 (2/1057)	1.000	
Total	73	6.9 (73/1057)	79	7.5 (79/1057)	0.924	0.766, 1.082

BacT/ALERT FN Plus: Blood – Compliant – Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	47	5.2 (47/912)	48	5.3 (48/912)	0.979	0.823, 1.135
Contaminant	13	1.4 (13/912)	10	1.1 (10/912)	1.300	
Unknown	0	0.0 (0/912)	0	0.0 (0/912)	-	
Total	60	6.6 (60/912)	58	6.4 (58/912)	1.034	0.852, 1.216

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BacT/ALERT PF Plus: Blood - Compliant – Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	1	0.6 (1/161)	1	0.6 (1/161)	1.000	-1.772, 3.772*
Contaminant	0	0.0 (0/161)	0	0.0 (0/161)	-	
Unknown	0	0.0 (0/161)	0	0.0 (0/161)	-	
Total	1	0.6 (1/161)	1	0.6 (1/161)	1.000	-1.772, 3.772*

*Since the confidence interval contains a negative value and the ratio cannot be negative, the interval does not provide a meaningful interpretation.

Low Fill BacT/ALERT FA Plus: Blood – Compliant – Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	28	7.4 (28/379)	29	7.7 (29/379)	0.966	0.790, 1.142
Contaminant	4	1.1 (4/379)	3	0.8 (3/379)	1.333	
Unknown	1	0.3 (1/379)	0	0.0 (0/379)	-	
Total	33	8.7 (33/379)	32	8.4 (32/379)	1.031	0.790, 1.272

BacT/ALERT SA: Blood Culture – Compliant – Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	40	5.1 (40/780)	39	5.0 (39/780)	1.026	0.857, 1.195
Contaminant	4	0.5 (4/780)	10	1.3 (10/780)	0.400	
Unknown	2	0.3 (2/780)	1	0.1 (1/780)	2.000	
Total	46	5.9 (46/780)	50	6.4 (50/780)	0.920	0.736, 1.104

Section 1.10

BacT/ALERT SN: Blood – Compliant – Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	32	3.9 (32/830)	30	3.6 (30/830)	1.067	0.797, 1.337
Contaminant	1	0.1 (1/830)	4	0.5 (4/830)	0.250	
Unknown	1	0.1 (1/830)	0	0.0 (0/830)	-	
Total	34	4.1 (34/830)	34	4.1 (34/830)	1.000	0.730, 1.270

The following tables compare results of the BacT/ALERT VIRTUO to BacT/ALERT 3D sterile body fluid cultures that yielded single or multiple isolates on subculture.

BacT/ALERT FA Plus: SBF - Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	42	11.2 (42/374)	42	11.2 (42/374)	1.000	0.852, 1.148
Contaminant	8	2.1 (8/374)	6	1.6 (6/374)	1.333	
Unknown	5	1.3 (5/374)	4	1.1 (4/374)	1.250	
Total	55	14.7 (55/374)	52	13.9 (52/374)	1.058	0.864, 1.252

BacT/ALERT FN Plus: SBF - Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	39	8.9 (39/437)	38	8.7 (38/437)	1.026	0.838, 1.214
Contaminant	9	2.1 (9/437)	8	1.8 (8/437)	1.125	
Unknown	4	0.9 (4/437)	6	1.4 (6/437)	0.667	
Total	52	11.9 (52/437)	52	11.9 (52/437)	1.000	0.794, 1.206

Section 1.10

BacT/ALERT SA: Sterile Body Fluids - Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	14	18.2 (14/77)	15	19.5 (15/77)	0.933	0.807, 1.059
Contaminant	0	0.0 (0/77)	2	2.6 (2/77)	0.000	
Unknown	1	1.3 (1/77)	0	0.0 (0/77)	-	
Total	15	19.5 (15/77)	17	22.1 (17/77)	0.882	0.665, 1.099

BacT/ALERT SN: Sterile Body Fluids - Single and Multiple Isolates

Clinical Determination	VIRTUO True Positives	% of VIRTUO True Positives in Population	BTA3D True Positives	% of BTA3D True Positives in Population	Ratio of True Positives	95% CI (LCL, UCL)
Significant	17	21.0 (17/81)	17	21.0 (17/81)	1.000	0.837, 1.163
Contaminant	1	1.2 (1/81)	1	1.2 (1/81)	1.000	
Unknown	1	1.2 (1/81)	0	0.0 (0/81)	-	
Total	19	23.5 (19/81)	18	22.2 (18/81)	1.056	0.806, 1.306

When all 5862 bottle pairs tested are considered, false positive rates were 0.09% (5/5862) and 0.19% (11/5862) for VIRTUO and BTA3D, respectively. False negative rates were 0.38% (22/5862) and 0.38% (22/5862) for VIRTUO and BTA3D, respectively. While the algorithm on VIRTUO is new and has some differences compared to that of the BTA3D, these results for VIRTUO and BTA3D demonstrate an equivalent ability of the two systems to detect and recover organisms in BacT/ALERT bottles and demonstrate the efficacy of the VIRTUO Detection algorithm. The yields of microorganisms are similar between VIRTUO and BTA3D.

There were 1490 positive controls tested on VIRTUO for all sites combined. Of those, 1487 (99.8%) were signaled positive by VIRTUO. There were 1486 negative controls tested for all sites combined. Of those, 1486 (100%) were signaled negative by VIRTUO. Of the total of 2976 controls tested over the course of the clinical trial, VIRTUO gave the expected result for 2973/2976 (99.9%) of the controls.