K121455

BIOMÉRIEUX

510(k) SUMMARY

JAN 25 2013

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

Name of device

BacT/ALERT® FN Plus

Device Identification

Trade Name: BacT/ALERT® FN Plus Culture Bottle

Classification Name: Blood Culturing System, Microbiology

Product Code: MDB

Regulation: 21CFR866.2560, microbial growth monitor

Device Class: Class 1, not exempt from premarket notification per 21CFR807.81

Premarket Notification Submitter

Company Name:	bioMérieux, Inc.
Company Address:	100 Rodolphe Street
	Durham, NC 27712
Contact:	Patricia Murphy, Staff Regulatory Affairs Specialist
Telephone #	919-620-2270
Fax#	919-620-2548
Preparation Date:	May 14, 2012

Intended Use of the Device:

BacT/ALERT® FN Plus Culture Bottles are used with the BacT/ALERT® Microbial Detection System in qualitative procedures for recovery and detection of anaerobic and facultative anaerobic microorganisms from blood and other normally sterile body fluids.

Description of the Device:

The proposed resin formulation reagent (BacT/ALERT® FN Plus Culture Bottle) is an improvement upon the cleared charcoal formulation reagent (BacT/ALERT® FN Culture Bottle). The BacT/ALERT® FN Culture Bottles are used with the BacT/ALERT® Microbial Detection Systems in qualitative procedures for recovery and detection of microorganisms from blood.

The predicate BacT/ALERT® FN Culture Bottle contains charcoal in the complex growth medium for its antimicrobial neutralization properties. Charcoal is eliminated in the proposed BacT/ALERT® FN Plus Culture Bottle, and is replaced with two types of adsorbent polymeric beads in the complex growth medium. The proposed BacT/ALERT® FN Plus Culture Bottle (resin) is optimized to increase antimicrobial neutralization properties and to increase the clarity of Gram stains in comparison to the predicate BacT/ALERT® FN Culture Bottle (charcoal) while maintaining the ability to detect and recover microorganisms.

The BacT/ALERT® Microbial Detection System provides both a microbial detection system and a culture medium bottle with suitable nutritional and environmental conditions for microorganisms commonly encountered in blood or other normally sterile body fluid samples (except urine) taken from a patient suspected of having bacteremia/fungemia. An inoculated bottle is placed into the instrument where it is incubated and continuously monitored for the presence of microorganisms that will grow in the BacT/ALERT® bottles.

The BacT/ALERT® Microbial Detection System utilizes a colorimetric sensor and reflected light to monitor the presence and production of carbon dioxide (CO_2) that is dissolved in the culture medium. If microorganisms are present in the test sample, carbon dioxide is produced as the microorganisms 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 lighter color results in an increase of reflectance units monitored by the system. Bottle reflectance is monitored and recorded by the instrument every 10 minutes.

SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate device name(s):

BacT/ALERT® FN Culture Bottle

Predicate device 510(k) number(s)

K020815

Comparison with predicate

The BacT/ALERT FN Plus Culture Bottle is claimed substantially equivalent to the BacT/ALERT FN Culture Bottle (**K020815**).

Table 1 Similarities and differences between the bottles are outlined below:

Culture Bottle Characteristics: Changes versus K020815	
Specimen Sampling and Handling	Unchanged
Assay Types	Unchanged
Reaction Types	Unchanged
Calibration	Unchanged
Quality Control (by Operator)	Unchanged
Principles of Operation	Unchanged
Firmware	No changes to software code (in detection software) occurred. Released with firmware version B.40 on BacT/ALERT Microbial Detection Systems The structure of the detection algorithm remains unchanged. No change was made to the initial value threshold of the BacT/ALERT® FN Plus bottle type knowledge base. Applicable variables in software controlling barcode recognition were adjusted to enable recognition of the new bottle type.

Performance Characteristics

Analytical Testing

Analytical Sensitivity: Growth Performance

Data represent results from in-house seeded studies with and without blood obtained from healthy human volunteers. Multiple strains were tested for each species at target inoculum levels of 125 CFU per bottle. The species listed are representatives of clinically prevalent organisms in blood cultures and sterile body fluids.

Table 2 Growth Performance Results

Microorganism	Blood				No Blood			
	% Recovery (n)	Range CFU/bottle	Time to Detection (hours)		% Recovery* (n=3)	Range CFU/bottle	Time to Detection (hours)	
			Mean	Range			Mean	Range
Staphylococcus aureus	100.0 (15/15)	54 - 150	14.6	12.9 – 16.7	100	116 - 150	21.8	21.3 – 22.0
Escherichia coli	100.0 (15/15)	73 - 254	10.9	10.4 – 12.4	100	73 - 176	11.6	10.4 – 12.9
Bacteroides fragilis	100.0 (18/18)	9 - 154	29.7	24.3 - 43.6	66.7 (2/3)	19 - 154	97.2	79.2 - 115.2
Streptococcus	100.0	4 - 260	16.5	11.5 - 43.8	100	4 - 25	17.5	16.0 –

pneumoniae	(15/15)							19.3
Clostridium perfringens	100.0 (18/18)	58 - 210	17.3	12.0 - 40.1	100.0 (8/8)	76 - 210	27.1	14.1 - 35.7
Klebsiella pneumoniae	100.0 (15/15)	89 - 123	11.2	10.4 - 13.1	100	95 - 123	12.6	12.1 - 13.4
Fusobacterium nucleatum	70.6 (12/17)	19 - 204	74.4	36.0 - 108.0	75.0 (3/4)	19 - 116	56.1	41.2 - 64.8
Streptococcus agalactiae	100.0 (15/15)	14 - 194	16.9	12.7 - 28.9	100	21 - 34	25.9	20.5 - 33.4
Enterococcus faecalis	100.0 (15/15)	63 - 259	13.7	11.9 - 19.4	100	71 - 169	22.4	17.8 - 24.8
Parvimonas micra	80.0 (16/20)	46 - 154	51.4	37.3 - 69.6	0.0 (0/4)	46 - 154	-	-
Enterobacter cloacae	100.0 (15/15)	111 - 200	11.9	11.1 - 12.5	100	111 - 185	13	11.9 - 14.7
Proteus mirabilis	100.0 (15/15)	36 - 213	11.4	10.9 - 12.5	100	36 - 213	11.9	11.5 - 12.7
Eggerthella lenta	86.7 (13/15)	83 - 175	41	34.8 - 60.0	66.7 (2/3)	83 - 151	46	44.0 - 48.0
Staphylococcus epidermidis	100.0 (15/15)	44 - 135	21	17.4 - 25.3	100	44 - 105	29.3	24.5 - 36.8
Listeria monocytogenes	100.0 (15/15)	121 - 251	17.1	15.5 - 19.3	100	121 - 251	19.2	17.7 - 20.3
Clostridium tertium	100.0 (15/15)	24	12.5	11.4 – 13.5	100	24	14.8	14.1 – 16.0
Clostridium septicum	50.0 (20/40)	25 - 146	31.7	13.9 – 62.4	40.0 (2/5)	90 - 146	43.4	17.1 – 69.6
Peptoniphilus asaccharolyticus	60.0 (12/20)	49 - 296	50.9	34.4 – 79.2	25.0 (1/4)	81 - 296	44.7	-

Less than 100% detection was observed for some species, to include *Capnocytophaga ochracea, Cardiobacterium hominis, Haemophilus parainfluenzae,* and *Granulicatella adiacens.*

*In case of less than 100% recovery, it is recommended to add blood such as sterile defibrinated horse blood (10% v/v).[3]

Antimicrobial Neutralization

Neutralization of antimicrobials by adsorbent polymeric beads varies depending upon dosage level and timing of specimen collection. Internal studies have demonstrated that antimicrobials are effectively neutralized by the BacT/ALERT FN Plus medium based on 100% recovery of organisms tested. In these tests,

antimicrobials were added in clinically relevant concentrations directly to culture bottles during inoculation with susceptible strains of obligate and facultative anaerobic microorganisms. The effectiveness of the antimicrobials was confirmed by parallel testing using a non-neutralizing medium as a control. Studies demonstrated that the following antimicrobials/antimicrobial categories were neutralized by the medium: imipenem, meropenem, oxacillin, glycylcycline, macrolides, cefoxitin, ceftaroline, aminoglycosides, fluoroquinolones, lincosamides, ketolides, and glycopeptides.

Antimicrobial neutralization was not achieved for ceftazidime, ceftriaxone, or cefepime.

Less than complete neutralization was observed for cefotaxime, cefazolin, ampicillin, penicillin, and ertapenem. Cefotaxime was neutralized at ranges of 40% peak serum level (PSL) to 3% PSL depending on the microorganism. Cefazolin was neutralized at ranges of 25% PSL to 5% PSL depending on the microorganism. Ertapenem was neutralized at 5% PSL. Ampicillin was neutralized at 75% PSL for. *E. faecalis*. Penicillin was neutralized at 120% PSL for *S. pneumoniae*. No neutralization was observed for *C. perfringens* at 100% PSL of either ampicillin or penicillin.

Potentially Interfering Substances

In-house seeded studies were conducted with cerebrospinal fluid, pleural fluid, synovial fluid, plasma, blood, and blood clots. Aliquots of each of these fluids also received white blood cells at concentrations relevant to bacteremia in each given body fluid. White blood cells and blood clots were added because sepsis can lead to elevation of white blood cells and activation of the coagulation cascade. Testing was conducted with and without microorganisms. These substances neither interfered with recovery and detection of organisms, nor did they generate false positive results in the absence of organisms.

Limit of Detection (LoD)

Data in Table 3 shows results from in-house seeded studies. A minimum of 30 replicates were tested per species. Data in Table 3 was generated using bottles at end of shelf life. Bottles inoculated with *B. fragilis* and *S. pneumoniae* received 1 ml pooled human blood supplementation. At least 95% detection was achieved at LoD.

Table 3 Summary of LoD Data

Microorganism	Strain ID	LoD (CFU/bottle)

Bacteroides fragilis	ATCC 25285	5
Clostridium perfringens	NCTC 8798	4
Enterobacter aerogenes	ATCC 13048	8
Enterococcus faecalis	NCTC 12697	4
Escherichia coli	NCTC 12923	4
Listeria monocytogenes	ATCC 15313	6
Salmonella enterica	ATCC 14028	5
Staphylococcus aureus	NCTC 10788	4
Streptococcus pneumoniae	ATCC 6305	6

Within Laboratory Precision (Repeatability)

Data represents results from in-house seeded studies conducted on 12 days on multiple instruments by multiple operators. Organisms were grown in the presence of clinically relevant concentrations of antimicrobials to which they are susceptible. In this seeded study BacT/ALERT FN Plus bottles were subcultured at least 24 hours after being flagged positive by the instrument. A minimum of 108 replicates were tested for each organism/antimicrobial combination.

Table 4 Summary of the Within-Laboratory Precision Data

Sample Input		CFU/bottle (range)	% Recovery				Time to Detection (hours)	
Organism	Antimicrobial		Lot 1	Lot 2	Lot 3	Overall	Mean	Range
B. fragilis	Imipenem	136 - 406	100.0	100.0	100.0	100.0	36.9	30.2 – 55.2
C. perfringens	Vancomycin	75 - 204	100.0	94.4	100.0	98.2	14.5	11.1 – 22.0
S. aureus	Oxacillin	94 - 158	100.0	100.0	100.0	100.0	17.7	15.1 – 24.3

Reproducibility

Data represents results from seeded studies conducted at three sites using a target of 144 replicates per site on 3 days with a minimum of two operators per site. Reproducibility was evaluated on each of 8 organisms. One organism (*S. pneumoniae*) was prepared via serial dilution and the other 7 organisms were prepared using BioBalls. *S. pneumoniae* was seeded into the FN Plus bottle at a target inoculum of 100 CFU/bottle, with an acceptable range of 30-300 CFU/bottle and the other 7 organisms at a target range of 1-17 CFU/bottle. The actual inoculum ranged from 5 CFU/bottle to 500 CFU/bottle for the 30-300

CFU/bottle range, and from 1 CFU/bottle to 270 CFU/bottle for the 1-17 CFU/bottle range. Percent recovery reflects positive flag by the instrument and Gram stain/subculture consistent with the seeded organism.

Table 5 Summary of Reproducibility Data

Sample Input	% Agreement to Expected*				Time to Detection		Inoculum Range (CFU/bottle)
	Site 1	Site 2	Site 3	Overall	Mean	Range	
Staphylococcus aureus	96.3% (26/27)	79.2% (19/24)	100.0% (33/33)	92.9% (78/84)	20.2	18.5-35.7	2-12
Escherichia coli	100.0% (18/18)	79.2% (19/24)	100.0% (33/33)	93.3% (70/75)	12.8	11.4-20.8	2-11
Enterococcus faecalis	100.0% (30/30)	83.3% (20/24)	97.0% (32/33)	94.3% (82/87)	24.6	17.9-30.4	2-15
Clostridium perfringens	100.0% (18/18)	96.8% (61/63)	100.0% (30/30)	98.2% (109/111)	12.2	10.2-17.3	3-122
Enterobacter aerogenes	90.0% (27/30)	75.0% (18/24)	90.5% (38/42)	86.5% (83/96)	14.6	11.9-16.7	1-270
Listeria monocytogenes	100.0% (21/21)	100.0% (24/24)	100.0% (33/33)	100.0% (78/78)	22.8	20.6-37.0	1-13
Salmonella enterica	100.0% (24/24)	79.2% (19/24)	100.0% (30/30)	93.6% (73/78)	13.3	12.4-14.4	1-16
Streptococcus pneumoniae	100.0% (30/30)	100.0% (36/36)	100.0% (18/18)	100.0% (84/84)	17.5	13.3-23.1	5-500
Overall	**98.0% (194/198) 95% CI: 94.9%, 99.5%**	**88.9% (216/243) 95% CI: 84.3%, 92.6%**	**98.0% (247/252) 95% CI: 95.4%, 99.4%**	**94.8% (657/693) 95% CI: 92.9%, 96.3%**			

The above data includes repeat testing performed as a result of laboratory errors at a single site (i.e. contaminated bottles/reagents, colony counts out of range and site failure to change bottle status after positive instrument signal and positive subculture). Data excluding the laboratory errors, demonstrated 100% recovery with the exception of *E. aerogenes* which exhibited 96.3% recovery for all sites combined.

Delayed Entry

Results from seeded studies using 6 species*, at target concentrations of 100 CFU/bottle (acceptable range of 30-300 CFU/bottle) were generated at three sites. Actual inoculum levels ranged from 41 CFU/bottle to 253 CFU/bottle. All bottles contained human blood from healthy volunteers and were held at specified temperatures and times prior to loading into the BacT/ALERT instrument. Percent recovery reflects positive flag by the instrument and Gram stain/subculture consistent with the seeded organism.

Table 6 Summary of Delayed Entry Data

Sample Input	Incubation Temperature (°C)	Hold Time (hours)	% Recovery	Time to Detection from Sample Inoculation (Hold Time + Instrument TTD in hours)	
				Mean	Range
Inoculated Test Bottles	Control	No delay	100.0% (89/89)	15.9	9.5 - 52.8
	2-8	48	100.0% (65/65)	63.3	50.1 - 90.4
	20-25	24	100.0% (62/62)	34.7	26.0 - 79.2
	20-25	36	100.0% (62/62)	43.6	38.0 - 78.6
	35-37	8	100.0% (72/72)	17.7	10.0 - 53.4
	35-37	24	80.0% (64/80)	28.6	26.0 - 52.3
Negative Controls	All conditions		0.0% (0/51)	-	-

**Staphylococcus aureus, Escherichia coli, Streptococcus pneumoniae, Enterococcus faecium, Bacteroides fragilis, Clostridium perfringens*

CAUTION: Culture bottles held at 35 to 37°C for 24 hours or longer before loading may not detect microorganisms and should be subcultured.

Clinical Study Results (Blood Culture)

A multi-center clinical study was conducted at three different geographic sites in the U.S. comparing performance of the FN Plus and FN blood culture bottles for anaerobic culture pairs that received blood volumes between 6 ml and 10 ml (compliant pairs). A total of 2514 anaerobic bottle pairs were obtained from 1080 adult patients suspected of blood stream bacterial/yeast infections. Subcultures of both bottles were performed for any bottle in the set determined to be positive by the BacT/ALERT system. A pair of bottles was determined to have a positive status if subculture of either the FN Plus or FN bottle was positive. A culture bottle was determined to be a "True Positive" if the culture was flagged positive by the BacT/ALERT System and resulted in growth of the isolate upon subculture

of this bottle. True positive rates were calculated for the FN Plus and FN culture bottles and the ratio of FN Plus true positives to FN true positives was calculated to compare performance. Clinical Isolates recovered were classified as significant, contaminant, or unknown based on determination by the clinical trial sites.

A total of 312 isolates were recovered from all compliant anaerobic blood culture pairs with a positive status. There were a total of 289 bottle pairs that recovered at least 1 isolate by subculture of FN Plus or FN bottles. A total of 266 bottle pairs recovered a single isolate and 23 bottle pairs recovered two isolates. The total population reported in Table 7 comprises the 312 isolates recovered from positive bottle pairs and 2225 negative bottle pairs for a total of 2537 results. The FN Plus bottle detected a total of 282 isolates compared to the FN bottle that detected 192 isolates. Of the significant isolates, the FN Plus bottle detected a total of 202 isolates compared to the FN bottle that detected 150 significant isolates. Three false positives were identified on subculture of positive FN Plus bottles and comprised 0.12% (3/2537) of the study population.

Table 7 All Compliant Pairs With Single and Multiple Isolates Combined (Blood Cultures)

Clinical Determination	FN Plus True Positives	% of FN Plus True Positives in Population	FN True Positives	% of FN True Positives in Population	Ratio of True Positives
Significant	202	8.0% (202/2514)	150	6.0% (150/2514)	1.347
Contaminant	58	2.3% (58/2514)	30	1.2% (30/2514)	1.933
Unknown	22	0.9% (22/2514)	12	0.5% (12/2514)	1.833
Total	*282*	*11.2% (282/2514)*	*192*	*7.6% (192/2514)*	1.469

One hundred sixty two (162) isolates were detected by both FN Plus and FN. 120 isolates were detected only by FN Plus and 30 isolates were detected only by FN. *The ratio of true positive rates for overall isolates was 1.469 (282/192) with a 95% CI of (1.317, 1.621)[7].

Clinical Study Results – (Sterile Body Fluid Cultures)

A multi-center clinical study was conducted at four different geographic sites in the U.S. and Canada comparing the performance of the FN Plus and FN culture bottles with sterile body fluid specimens (SBF). A total of 339 bottle pairs were obtained from 310 adult patients suspected of SBF bacterial/yeast infections. Sterile body fluid types evaluated were amniotic fluid, continuous ambulatory peritoneal dialysis (CAPD) fluid, cerebrospinal fluid (CSF), peritoneal fluid, pleural fluid, and synovial fluid. Clinical Isolates recovered were classified as significant, contaminant, or unknown based on determination by the clinical trial sites.

A total of 77 isolates were recovered from all anaerobic SBF culture pairs with a positive status. There were a total of 61 bottle pairs that recovered at least 1 isolate by subculture of FN Plus or FN bottles. A total of 50 bottle pairs recovered a single isolate, 7 bottle pairs recovered two isolates, 3 bottle pairs recovered 3 isolates, and 1 bottle pair recovered 4 isolates. The total population reported in Table 8 comprises the 77 isolates recovered from positive bottle pairs and 278 negative bottle pairs for a total of 355 results. The FN Plus bottle detected a total of 72 isolates compared to the FN bottle that detected 59 isolates. Of the significant isolates, the FN Plus bottle detected a total of 52 isolates compared to the FN bottle that detected 50 isolates. No false positives were identified for the FN Plus bottle from the study population (0/355).

Table 8 below compares results of the BacT/ALERT FN Plus to BacT/ALERT FN SBF cultures that yielded single or multiple isolates on subculture.

Table 8 All Pairs With Single and Multiple Isolates Combined (Sterile Body Fluid Cultures)

Clinical Determination	FN Plus True Positives	% of FN True Positives in Population	FN True Positives	% of FN True Positives in Population	Ratio of True Positives
Significant	52	15.3% (52/339)	50	14.7% (50/339)	1.040
Contaminant	12	3.5% (12/339)	2	0.6% (2/339)	6.000
Unknown	8	2.5% (8/339)	7	2.1% (7/339)	1.143
Total	*72*	*21.2% (72/339)*	*59*	*17.4% (59/339)*	1.220

Fifty four (54) isolates were detected by both FN Plus and FN. 18 isolates were detected only by FN Plus and 5 isolates were detected only by FN. The ratio of true positive rates for overall isolates was 1.220 (72/59) with a 95% CI of (1.044, 1.396)[7]

Proposed Labeling

The proposed labeling is complete.

Conclusion:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

JAN 25 2013

bioMerieux, Inc.
c/o Patricia (Trish) Murphy
Staff Regulatory Affairs Specialist
100 Rodolphe Street
Durham, NC 27712

Re: k121455
Trade/Device Name: BacT/ALERT® FN Plus Culture Bottle
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial Growth Monitor
Regulatory Class: Class I
Product Code: MDB
Dated: January 11, 2013
Received: January 14, 2013

Dear Ms. Murphy:

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.

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); 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 regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

INTENDED USE STATEMENT

510(k) Number (if known): K121455

Device Name: BacT/ALERT® FN Plus Culture Bottles

Intended Use:

BacT/ALERT® FN Plus Culture Bottles are used with the BacT/ALERT® Microbial Detection System in qualitative procedures for recovery and detection of anaerobic and facultative anaerobic microorganisms from blood and other normally sterile body fluids.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

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