K123947

510(k) Summary

The summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Company and Contact Name

Mr. Joan Guixer, Director of Quality Assurance and Regulatory Affairs
Biokit S.A.
Llica d'Amunt
Barcelona, Spain 08186
Phone: +34657883347/+34 93 860 9000
Fax: +34 93 860 9029

AUG 2 9 2013

Date Prepared: August 27, 2013

Regulatory Declarations

Common/Usual Name	Vancomycin Test
Trade/Proprietary Name	ARCHITECT *i* Vancomycin
Classification Regulation	21 CFR 862.3950
Device Class	Class II
Device Regulation Panel	Toxicology
Product Code	LEH

Indications for Use

The ARCHITECT *i* Vancomycin assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of vancomycin in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The ARCHITECT *i* Vancomycin assay is used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to help ensure appropriate therapy.

Legally Marketed Device to Which Equivalency is Claimed

The ARCHITECT *i* Vancomycin assay (LN 1P30-28) is substantially equivalent to the previously cleared ARCHITECT *i* Vancomycin assay (LN 1P30-25, K072036).

Device Description

The ARCHITECT *i* Vancomycin assay is a one-step *STAT* immunoassay for the quantitative measurement of vancomycin in human serum or plasma using CMIA technology, with flexible assay protocols, referred to as Chemiflex.

Sample, anti-vancomycin coated paramagnetic microparticles, and vancomycin acridinium-labeled conjugate are combined to create a reaction mixture. The anti-vancomycin coated microparticles bind to vancomycin present in the sample and to the vancomycin acridinium-labeled conjugate. After washing, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of vancomycin in the sample and the RLUs detected by the ARCHITECT *i* System optics.

Comparison of Technological Characteristics

Both the submission (ARCHITECT *i* Vancomycin [LN 1P30-28]) and predicate (ARCHITECT *i* Vancomycin [LN 1P30-25]) device use a chemiluminescent microparticle immunoassay (CMIA) technology for the quantitative measurement of vancomycin in human serum and plasma.

Summary of Performance Testing

Precision

Vancomycin samples were tested for precision following the CLSI protocol EP5-A2. In the study, the total run %CV was $\leq$ 10% and meets the design acceptance criteria.

Recovery

Serum samples were spiked with vancomycin at concentrations across the assay range. The overall percent recovery of the ARCHITECT *i* Vancomycin assay was 100.2%. The percent recovery ranged from 98.0% to 105.4% for vancomycin concentrations from 5 to 45 µg/mL. The percent recovery was 86.4% for vancomycin concentration 3.2 µg/mL.

Interferences

Serum specimens with vancomycin levels from 4.4 to 48.8 µg/mL were supplemented with the following potentially interfering compounds. The mean recovery observed during the study ranged from 93.0% to 104.5%.

- Triglycerides, 2500 mg/dL
- Hemoglobin, 400 mg/dL
- Bilirubin, 20 mg/dL
- Low Protein, 3 g/dL
- High Protein, 12 g/dL
- HAMA, 1000 ng/mL
- Rheumatoid Factor, 500 IU/mL

Linearity

Samples were tested to demonstrate linearity throughout the assay range. A linear range of 3.0 µg/mL to 50.0 µg/mL was established for the ARCHITECT *i* Vancomycin assay.

Sensitivity

In this study, the Limit of Blank (LoB) was 0.27 µg/mL, Limit of Detection (LoD) was 0.42 µg/mL and Limit of Quantitation (LoQ) was 2.50 µg/mL.

Matrix Comparison

The specimen collection tubes listed below were verified to be used with the ARCHITECT *i* Vancomycin assay.

- Human serum
- Human plasma collected in:
    - Lithium heparin
    - Dipotassium EDTA
    - Sodium Citrate
    - Sodium Heparin
    - Sodium Fluoride/Potassium Oxalate

Specificity

A study has demonstrated that vancomycin crystalline degradation product 1 (CDP-1) at a concentration of 10 µg/mL, has cross-reactivity less than 0.42 µg/mL in the absence of vancomycin. CDP-1 at ≥ 5 µg/mL demonstrated cross-reactivity with samples containing vancomycin in the measurement range. CDP-1 may accumulate in patients with impaired renal function.

The following compounds were tested in the absence of vancomycin after adding 500 µg/mL of each compound (except Methotrexate, Isoniazid and CDP-1) to human serum. Isoniazid was tested at 300 µg/mL. Methotrexate was tested at 227 µg/mL. Cross-reactivity of each compound was less than 0.42 µg/mL. The same compounds (except CDP-1 and Isoniazid) at the concentrations tested demonstrated no interference in the presence of vancomycin using the acceptance criteria of % recovery within 100 ± 10%. Interference was observed for CDP-1 and Isoniazid in the presence of vancomycin as follows:

- CDP-1 at ≥ 5 µg/mL interferes with samples containing vancomycin in the measurement range.
- Isoniazid at > 300 µg/mL interferes with samples containing vancomycin in the measurement range.

Acetaminophen	Clindamycin	Heparin	Nitrofurantoin	Sulfamethoxazole
Amikacin	Chloramphenicol	Hydrocholorothiazide	Penicillin G	Tetracycline
Amphotericin B	Chlorothiazide	Ibuprofen	Penicillin V	Ticarcillin
Ampicillin	Ciprofloxacin	Isoniazid	Prednisolone	Tobramycin
Caffeine	Erythromycin	Kanamycin B	Rifampin	Trimethoprim
CDP-1	Ethambutol	Methotrexate	Salicylic acid	
Cefotaxime	5-Fluorocytosine	Methylprednisolone	Spectinomycin	
Cephalexin	Furosemide	Naproxen	Streptomycin	
Cephalothin	Gentamicin	Neomycin	Sulfadiazine	

Method Comparison

The new ARCHITECT *i* Vancomycin assay (LN 1P30-28) correlated with the predicate ARCHITECT *i* Vancomycin assay (LN 1P30-25) as shown in the table below:

Specimen Concentration Range (µg/mL)		Number of Observations	Correlation Coefficient (r) (95% CI)	Slope (95% CI)	Intercept (95% CI)
LN 1P30-25	LN 1P30-28				
7.34-47.49	7.69-48.60	107	0.99 0.99, 0.99	1.04 1.01, 1.07	-0.23 -0.87, 0.36

Measuring Interval

For the verification studies described in the reagent package insert, the measuring interval range is 3.0 µg/mL to 50.0 µg/mL.

Conclusion

Substantial equivalence of the proposed device to the previously cleared ARCHITECT *i* Vancomycin assay (K072036) has been demonstrated through performance testing to verify that the device functions as intended and design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

Biokit S.A.
C/O Joan Guixer
Can Malé S/N
Llicá d'Amunt, Barcelona, 08186, SPAIN

Re: K123947
Trade/Device Name: ARCHITECT iVancomycin
Regulation Number: 21 CFR 862.3950
Regulation Name: Vancomycin test system
Regulatory Class: II
Product Code: LEH
Dated: July 23, 2013
Received: July 25, 2013

Dear Mr. Guixer:

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 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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123947

Device Name: ARCHITECT *i* Vancomycin

Indications for Use:

Reagents

The ARCHITECT *i* Vancomycin assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of vancomycin in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The ARCHITECT *i* Vancomycin assay is used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to help ensure appropriate therapy..

For *in vitro* diagnostic use.

Prescription Use __X__ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.08.28 13:21:25 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123947