corgenix

K062025

510(K) Summary
[As required by 21 CFR 807.92(c)]

MAY 2 9 2007

Submitter's Name and Address:
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Date Summary Prepared: July 17, 2006, Revised on April 3, 2007
Device Proprietary Name: AspirinWorks® Test Kit (11-Dehydro Thromboxane B_2)
Regulation Name: Automated platelet aggregation system
Proposed Classification: 21 CFR 864.5700
Proposed Product Code: ~~JOZ~~ OBW
Predicate Device: Verify*Now*™ Aspirin Assay (K042423)

Device Description:
An ELISA for the detection of urinary 11-Dehydro Thromboxane B_2 (11dhTxB_2). Goat anti-mouse IgG polyclonal antibody (Jackson ImmunoResearch Laboratories, Inc, West Grove, PA) is coated onto 96-microwell plates. Reference, control, and patient samples are diluted in a Tris-based sample diluent (pH 9.0) and added to the microwells. An 11dhTxB_2 tracer (11dhTxB_2 linked to alkaline phosphatase, (AP); Cayman Chemical Company, Ann Arbor, MI) is then added to all wells except assay blanks, followed by the addition of an anti-11dhTxB_2 murine monoclonal antibody (Cayman Chemical Company) to all wells except assay blanks. The maximum binding wells (B_0) contain sample diluent, tracer, and monoclonal antibody, but no unlabeled 11dhTxB_2. The plate is then covered with the plastic sheet provided in the kit, and incubated at room temperature on a rotary shaker at 300-600 rpm for two hours. The AP-Tracer and unlabeled 11dhTxB_2 from the reference curve/controls/samples compete for binding to the anti-11dhTxB_2 monoclonal antibody, which is bound to the plate by the goat anti-mouse polyclonal antibody. After incubation, the reaction solution is removed from the wells followed by five washes with TBS/Tween 20. The pNPP substrate is then added and the plate is covered and incubated with shaking for 30 minutes. The reaction is stopped by the addition of Stop Solution (0.1M EDTA) to the wells, and the plate is read at 405-420 nm. Results are compared to the reference curve and expressed in pg/ml. Patient results are then normalized using the creatinine concentration of the sample, as measured by a separate assay.

Intended Use:
The AspirinWorks® Test Kit is an enzyme-linked immunoassay (ELISA) to determine levels of 11-Dehydro Thromboxane B_2 (11dhTxB_2) in human urine, which aids in the qualitative detection of aspirin effect in apparently healthy individuals post ingestion. For professional use only.

Technological Characteristics of the Device Compared to Predicate Device:
The AspirinWorks Test Kit was compared to the Accumetrics® VerifyNow™ Aspirin Assay (K042423) as the predicate device. The AspirinWorks Test Kit is a competitive enzyme-linked immunoassay (ELISA) that detects 11dhTxB_2 in urine. It is run in 96-well microtiter plates that have been coated with goat anti-mouse antibodies. To these wells samples, controls, or reference solution is added, followed by an 11dhTxB_2-alkaline phosphatase-linked tracer, and a monoclonal antibody specific for 11dhTxB_2. During the two-hour incubation, the 11dhTxB_2 monoclonal antibody forms a complex with either endogenous 11dhTxB_2 or the 11dhTxB_2 tracer, and this complex is bound to the plate by the anti-mouse antibodies. After washing, a substrate is added for 30 minutes, the reaction is terminated by addition of a stopping solution, and optical density at 405-420 nm is measured. The concentration of 11dhTxB_2 is indirectly proportional to the amount

of yellow color measured at 405-420 nm. 11dhTxB_2 is a metabolite of thromboxane A_2 (TxA_2), which is a potent inducer of platelet aggregation. Because TxA_2 has a short half-life, the more stable urinary 11dhTxB_2 metabolite is used as a direct measure of concentrations of TxA_2 and therefore platelet aggregation.

The Accumetrics VerifyNow Aspirin Assay is a turbidimetric-based optical detection system which measures platelet-induced aggregation. The system uses the agonist arachidonic acid to induce platelet response and is based on the ability of TxA_2-activated platelets to bind fibrinogen-coated beads. Light transmittance increases as activated platelets bind and aggregate the beads, and the instrument measures this change in optical signal caused by aggregation. The optical signal is measured as aspirin resistance units, or ARU (an arbitrarily assigned unit), and the normal response to aspirin results in ARU values of <550.

The manual AspirinWorks Test Kit measures urinary 11dhTxB_2, while the automated Accumetrics VerifyNow Aspirin Assay is a turbidimetric-based optical detection system which measures platelet-induced aggregation in whole blood. The two devices have similar intended uses in that they both measure aspirin effect. The AspirinWorks kit detects a metabolite of TxA_2, a direct inducer of platelet aggregation, while the Accumetrics kit measures *ex vivo* platelet aggregation caused by TxA_2 by artificially inducing aggregation and measuring an optical signal. Ultimately, both are analyzing aspirin's effect through the reduction of TxA_2 production or the resulting inhibition of platelet aggregation. Despite the differences between kits (manual vs. automated, urine vs. whole blood, ELISA vs. platelet aggregation turbidometry), no new issues of safety or effectiveness are raised as shown by the performance characteristics and predicate comparison between the two devices. Thus, the Accumetrics VerifyNow Aspirin Assay is a good predicate device for which to compare the AspirinWorks Test Kit. In addition, the AspirinWorks Test Kit minimizes the influence of preanalytical variables that may affect the Accumetrics device.

Summary of Non-Clinical and Clinical Studies:
Two different clinical studies were employed for the evaluation of the AspirinWorks Test Kit. Results from these studies established a cutoff for aspirin effect at ≤1500 pg 11dhTxB_2/mg creatinine. Further analysis revealed that 180/204 (88.2%) of samples from individuals not taking aspirin were above the cutoff value. Analysis of samples from individuals taking various doses of aspirin revealed that 7/163 (4.3%) of 81 mg/day aspirin users indicated a lack of aspirin effect (>1500 pg 11dhTxB_2/mg creatinine) and 4/38 (10.5%) of the 325 mg/day aspirin users indicated a lack of aspirin effect. In total, 11/201 (5.5%) of all aspirin users tested indicated a lack of aspirin effect. These percentages are consistent with those in published literature for aspirin non-responsiveness or lack of aspirin effect.

Non-clinical studies show a detection range for the AspirinWorks Test Kit of 300 – 4000 pg/mL, while intra- and inter-assay precision %CV's are all <20%. Recovery across the range of detection is within 10% of expected values, and no interference was caused by physiologically excessive concentrations of materials likely to be found in human urine. Finally, linearity testing at different sample dilutions confirmed that matrix effects do not affect measured levels of 11dhTxB_2.

The clinical and non-clinical studies demonstrate that the AspirinWorks Test Kit is a safe and effective method of determining levels of urinary 11dhTxB2 as an aid in the assessment of aspirin effect in apparently healthy individuals.

Kimberly Hassler
Director of Quality and Regulatory Affairs
2007-04-03
Date

Indications for Use Statement

510(k) Number: K062025

Device Name: AspirinWorks® Test Kit (11-Dehydro Thromboxane B_2)

Indications for Use:

The AspirinWorks® Test Kit is an enzyme-linked immunoassay (ELISA) to determine levels of 11-Dehydro Thromboxane B_2 ($11dhTxB_2$) in human urine, which aids in the qualitative detection of aspirin effect in apparently healthy individuals post ingestion. For professional use only.

The AspirinWorks® Test Kit is intended for use in clinical (hospital and reference) laboratories.

Prescription Use ✓ (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 IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 29 2007

Kimberly N. Hassler
Corgenix, Inc.
11575 Main Street, Suite 400
Broomfield, Colorado 80020

Re: k062025/S2
Trade/Device Name: AspirinWorks® Test Kit (11-Dehydro Thromboxane B_2)
Regulation Number: 21 CFR 864.5700
Regulation Name: Automated platelet aggregation system
Regulatory Class: Class II
Product Code: OBW
Dated: April 3, 2007
Received: April 4, 2007

Dear Ms. Hassler:

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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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