MeMed Diagnostics Ltd.
Efrat Hartog-David
VP of Regulatory Affairs and Quality Assurance
Nahum Heth 5
Tirat Carmel, 3508504
Israel

March 23, 2023

Re: K222332
Trade/Device Name: MeMed BV
Regulation Number: 21 CFR 866.3215
Regulation Name: Device To Detect And Measure Non-Microbial Analyte(S) In Human Clinical Specimens To Aid In Assessment Of Patients With Suspected Sepsis
Regulatory Class: Class II
Product Code: QPS
Dated: August 2, 2022
Received: August 2, 2022

Dear Efrat Hartog-David:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222332

Device Name
MeMed BV

Indications for Use *(Describe)*
The MeMed BV test is an automated semi-quantitative immunoassay that measures three non-microbial (host) proteins (TRAIL, IP-10, and CRP) in adult and pediatric serum samples and is intended for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial from viral infection. The MeMed BV is indicated for use in patients presenting to the emergency department or urgent care center and with samples collected at hospital admission from patients with suspected acute bacterial or viral infection, who have had symptoms for less than seven days. The MeMed BV test generates a numeric score that falls within discrete interpretation bins based on the increasing likelihood of bacterial infection.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

MeMed Diagnostics Ltd. MeMed BV® test

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

MeMed Diagnostics Ltd.

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Contact Person: Efrat Hartog-David, Ph.D,

Olga Boico, Ph.D

Date Prepared: August 2, 2022

Name of Device and Name/Address of Sponsor

MeMed BV® MeMed Diagnostics Ltd.

Nahum Heth 5 Tirat Carmel, 3508504, Israel

Common or Usual Name

MeMed BV®

Classification Name

Class II

Predicate Devices

MeMed BV by MeMed Diagnostics Ltd. (K210254)

Purpose of the Special 510(k) notice.

The Proposed modified MeMed BV® is a modification to Cleared MeMed BV®**.**

Intended Use/Indication for use

The MeMed BV® test is an automated semi-quantitative immunoassay that measures three non-microbial (host) proteins (TRAIL, IP-10, and CRP) in adult and pediatric serum samples and is intended for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial from viral infection. MeMed BV® is indicated for use in patients presenting to the emergency department or urgent care center and with samples collected at hospital admission from patients with suspected acute bacterial or viral infection, who have had symptoms for less than seven days. The MeMed BV® test generates a numeric score that falls within discrete interpretation bins based on the increasing likelihood of bacterial infection.

Device Description

The MeMed BV® ("BV Test" or the "Test") is an In-Vitro-Diagnostic device that measures in parallel the blood concentrations of TRAIL, IP-10 and CRP. The Test consists of an automated analyzer with built-in hardware and software that conduct chemiluminescence-based analyte measurements of patient serum samples and their computational integration (MeMed Key®), and a disposable cartridge that contains the reagents and controls needed to detect the analytes of interest (MeMed BV® cartridge). The Test generates an answer to each sample, with a test run time of approximately 15 minutes.

Technological Characteristics

The proposed modified MeMed BV® has similar technological characteristics as the cleared MeMed BV®, to which it is a modification. The modifications proposed are an alternative manufacturing process of the Antibody-Alkaline Phosphatase (Ab-AP) conjugation chemistry accompanied by a new Ab-AP conjugate buffer formulation solution. The aim of the introduction of the new chemistry is to enable manufacturing flexibility with additional sources of the chemistry without effecting the performance.

The test system is composed of the analyzer (MeMed Key®) and the cartridge, and their respective sub-components. The product is designed to allow straight forward sample-to-answer testing, with a test run time of approximately 15 minutes.

To operate the analyzer, the user turns on the MeMed-Key™ analyzer (or wakes-up the instrument if in standby mode), logs-in and selects the test. Users may log into the device using one of three assigned user levels and their corresponding passwords. The user ID and credentials are managed locally by each site. The firm will not have any control over the user IDs or credentials.

The patient's serum specimen is pipetted by the user into the designated cartridge area. The users are instructed to fill 100µl of sample. Each single-use cartridge is provided in a package that contains all necessary components for conducting a single patient test. This consists of the cartridge itself, all disposables (pipette tips), reagents and a waste collection well. The cartridge assembly contains both the reagents for the different assays and the pipette tips.

The cartridge is a multi-cavity plastic container that is sealed off with foil and covered with a label on the foil that indicates the sample type, the test name, indication to the user where to input the sample, required sample volume, lot number, cartridge expiry date and a barcode with test data and parameters that are intended to be read by the analyzer. The cartridge contains the several reagents in separate cavities, which are required to perform the test. Upon insertion of the cartridge, the analyzer conducts three immunoassays on a single serum sample of 100 μL. The cartridge also securely stores all waste materials collected during the test.

The user inserts the cartridge with sample into the analyzer and is guided by the carriage caddy. The analyzer auto-reads the cartridge's barcode and verifies that the requested test matches the cartridge type, cartridge expiration date, and that the calibration curve matches the cartridge lot number. The analyzer notifies the user when specimen processing is initiated and when the user should expect the test result.

After the cartridge has been inserted, the carriage caddy system locks and guides the cartridge during the insertion phase. The H-Bot then uses a hook to pull the cartridge in the rest of the way, at the same time rotating the Tip Holder 90 degrees exposing the pipette tips. The X axis robotic arm is used to move the thermal subsystem and cartridge holder in the X axis. Once loaded, the cartridge holder is driven by the X robot to the left, in position for processing.

The liquids are handled through the pipettor, which operates through measurement of displaced air volumes by means of a flow sensor, integrated directly in the pipetting head that is connected to a high-speed solenoid valve. The flow sensor is based on a differential pressure measurement across flow restriction. The cartridge is then heated through the heater block. A software-driven Proportional Integral Derivative (PID) control system is used to set and regulate the temperature of the heater block, using the center thermistor for feedback.

Once the sample has been diluted and mixed with magnetic particles, it is processed by the bead immobilizer magnet, which generates a high magnetic field strength, and allows both the reduction of immobilization time and a high percentage of bead retention per immobilization to be achieved. The sample is then washed and the chemiluminescence step takes place.

The chemiluminescence of the assay is measured by a Photo Multiplier Tube (PMT) Module, a highly sensitive light detection device. The selected PMT Module has a spectral range which matches the expected wavelength generated by the chemistry luminescence. The PMT notifies the analyzer software when the PMT is over-exposed to light. The PMT Module interfaces with the process-controller via several electrical connections. The process controller processes the input from the PMT to generate a “counts-per-seconds” signal which is the light-intensity measurement.

When a PMT reading is required, (typically of chemiluminescent sample in the tip) the robot moves the ADP mandrel into the PMT chamber (with or without tip) forming a light-tight seal. The software then turns the PMT Module on and a reading is taken. Once readings have been completed, the software automatically turns the PMT Module off. The ADP then retracts from the chamber and continues the assay process. The tip is ejected through movement of the ADP Mandrel and the Selenoid.

After completing the test, the analyzer notifies the user that the test workflow has ended successfully. The user removes the cartridge into a biohazard disposable container. In case of a failure, the system alerts the user. The alert settings are configurable.

Following successful completion of a test, the results are displayed\transferred to one or more of the following clients according to the user-selected configuration: Touch screen; LIS; Archive; External printer.

Calibration

The calibration is a process used to generate the calibration curve. The calibration curve translates RLU measurements to concentration of each analyte. A calibration is unique to a device and a cartridge lot. Each calibrator is a solution of the 3 analytes introduced as recombinant proteins.

The calibrators are in effect a synthetic sample which can be measured by the device using the normal cartridge. Calibrators are provided by MeMed in vials which need to be stored in normal refrigerators (2-8°C). The calibration workflow consists of three consecutive runs of the MeMed BV™ Test with the recombinant proteins in pre-determined concentrations as the sample. The calibration is valid only for a limited amount of time after the calibration takes place because the cartridge itself is decaying, producing different RLU measurements after a certain period (currently the calibration is valid for a period of 4 weeks). Every four weeks, or whenever a new lot needs to be used – the calibration process needs to be repeated.

Performance Data

The modified version of the MeMed BV has been tested according to the methods, protocols, and acceptance criteria used to support the previously 510(k)-cleared device. These methods apply to the device that is the subject of this Special 510(k) and were used in verification and validation ("V&V") of the modifications. The studies tested the performance of the measurement procedure for each individual measurand - CRP, IP-10, and TRAIL, as well as the performance of the measurement procedure for the MeMed BV® test score that is based on the computational integration of the three measurands.

Testing included precision/reproducibility, LoQ, linearity, hook effect, interference/cross-reactivity, and method comparison testing. All testing indicated equivalent performance to the 510(k)-cleared MeMed BV.

Substantial Equivalence

The modified MeMed BV® has the same intended use and similar indications, principles of operation, and technological characteristics as the originally 510(k)-cleared MeMed BV. The minor differences in the modified MeMed BV's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified MeMed BV is as safe and effective as the originally 510(k)-cleared MeMed BV. Thus, the modified MeMed BV is substantially equivalent to its predicate devices.

Conclusions

Risk analysis and testing results demonstrated that the proposed modified MeMed BV® is substantially equivalent to the predicate device.