January 17, 2018
Meso Scale Diagnostics, LLC
Lillian Quintero
Vice President, QA/RA
1601 Research Boulevard
Rockville, Maryland 20850

Re: K171498
Trade/Device Name: MSD CRP Assay Kit and MESO SECTOR S 700 Instrument
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN, DCK
Dated: November 30, 2017
Received: December 1, 2017

Dear Lillian Quintero:

This letter corrects our substantially equivalent letter of January 12, 2018.

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 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kelly Oliner -S

For,
Lea Carrington
Director
Division of Immunology
and Hematology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171498

Device Name
MSD® CRP Assay Kit

Indications for Use *(Describe)*
The MSD CRP Kit is intended for in vitro diagnostic use in the quantitative determination of C-reactive protein (CRP) in human serum using the MESO® SECTOR S 700 instrument. Measurement of CRP aids in the evaluation of infection, tissue injury, and inflammatory disorders. This test will be performed in a hospital or clinical laboratory setting by trained laboratory personnel. The target patient population for the MSD CRP Assay is symptomatic adults. Clinicians should utilize the results of the MSD CRP Assay for diagnosis of inflammatory diseases in conjunction with other clinical and laboratory findings.

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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Meso Scale Diagnostics, LLC.

510(k) Summary

Date Prepared:	January 8, 2018
510(k) Number:	K171498
Sponsor Name:	Meso Scale Diagnostics, LLC.
Address:	1601 Research Boulevard Rockville, Maryland 20850-3173
Contact Person:	Lillian Quintero, VP Quality Assurance/Regulatory Affairs
Telephone Number:	1-240-314-2600
Fax Number:	1-240-632-2219
Device Trade Name:	MSD® CRP Assay Kit and MESO® SECTOR S 700 Instrument
Common/Usual Name:	CRP Assay System
Product Code:	DCK, DCN
Classification Name:	C-reactive protein immunological test system 21 CFR 866.5270; Class II
Predicate Device:	Roche Diagnostics C-Reactive Protein (Latex) Assay and Roche Diagnostics Cobas Integra 800 Analyzer
Common/Usual Name:	CRP Assay System
Product Code:	DCK, DCN
Classification Name:	C-reactive protein immunological test system 21 CFR 866.5270; Class II
Premarket Notification:	K073277
Purpose for Submission:	New Device
Measurand:	C-Reactive Protein
Type of Test:	Electrochemiluminescence, Quantitative

Intended Use

MSD CRP Assay Kit

The MSD CRP Kit is intended for in vitro diagnostic use in the quantitative determination of C-reactive protein (CRP) in human serum using the MESO SECTOR S 700 instrument. Measurement of CRP aids in the evaluation of infection, tissue injury, and inflammatory disorders. This test will be performed in a hospital or clinical laboratory setting by trained laboratory personnel. The target patient population for the MSD CRP Assay is symptomatic adults. Clinicians should utilize the results of the MSD CRP Assay for diagnosis of inflammatory diseases in conjunction with other clinical and laboratory findings.

MESO SECTOR S 700 Instrument

The SECTOR S 700 instrument is intended for the in-vitro determination of analytes in bodily fluids. This instrument is not intended for Point-of-Care use.

Indication for use: Same as Intended Use

Special Conditions for Use Statement: For prescription use only

Special instrument requirements: The MESO SECTOR S 700

Device Description

The MSD CRP Assay Kit is a quantitative in-vitro diagnostic assay for conventional measurement of C-reactive protein in human serum. The CRP Assay Kit is designed for use with the MESO SECTOR® S 700 Instrument. The kit components include the 96-well CRP assay plate, CRP calibrator, CRP detection antibody, CRP diluent and CRP read buffer. The assay in the MSD CRP Kit is a sandwich immunoassay employing electrochemiluminescence (ECL) detection. In the instrument, a voltage is applied to the plate electrodes causing the captured labels to emit light. The instrument measures the intensity of emitted light from each spot to provide a quantitative measure of analyte in the sample.

Substantial Equivalence

Comparison with predicate:

Item	Device MSD CRP Assay Kit and MESO SECTOR S 700 Instrument	Predicate Roche Diagnostics C-Reactive Protein (Latex) Assay and Roche Diagnostics Cobas Integra 800 Analyzer
Intended Use/Indication for Use	The MSD CRP Kit is intended for in vitro diagnostic use in the quantitative determination of C-reactive protein (CRP) in human serum using the MESO SECTOR S 700 instrument. Measurement of CRP aids in the evaluation of infection, tissue injury, and inflammatory disorders. This test will be performed in a hospital or clinical laboratory setting by trained laboratory personnel. The target patient population for the MSD CRP Assay is symptomatic adults. Clinicians should utilize the results of the MSD CRP Assay for diagnosis of inflammatory diseases in conjunction with other clinical and laboratory findings.	Measurements of C-reactive protein aids in evaluation of the amount of injury to body tissues
Measurement	Quantitative	Same
Sample Type	Serum	Serum and Plasma

Item	Device MSD CRP Assay Kit and MESO SECTOR S 700 Instrument	Predicate Roche Diagnostics C-Reactive Protein (Latex) Assay and Roche Diagnostics Cobas Integra 800 Analyzer
Method	Sandwich-type electrochemiluminescence immunoassay	Particle-enhanced turbidimetric assay
Calibration	MSD CRP Calibrator	CRP T Control N Precinorm Protein (K012371) Precipath Protein (K012371)
Antibody	Mouse monoclonal anti-human CRP antibodies	Same
Assay Measuring Range (AMR)	3 – 160 mg/L	1 – 200 mg/L
Traceability	CRM474	CRM470

Standard/Guidance Document Referenced (if applicable):

- Guidance for Industry and FDA Staff – Review Criteria for Assessment of C-Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays, September 22, 2005
- CLSI EP05-A3, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition
- CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition
    - CLSI EP09-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition
    - CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
    - CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in The Clinical Laboratory; Approved Guideline – Third Edition

Test Principle:

The assay in the MSD CRP Kit is a sandwich immunoassay employing electrochemiluminescence (ECL) detection. This assay is carried out in a 96-well plate consumable that has integrated carbon ink electrodes screen-printed on the bottom of each well. The plate is provided pre-coated with capture antibody on a single, well-defined region of the electrode surface. The user adds the calibrator or sample and a solution containing detection antibody conjugated with electrochemiluminescent labels over the course of two incubation periods. Analyte in the sample binds to the capture antibodies immobilized on the electrode surface; recruitment of the detection antibodies by the bound analyte completes the sandwich. The user adds a buffer that creates the appropriate chemical environment for the electrochemiluminescent signal and loads the plate into an MSD MESO SECTOR S 700 instrument. In the instrument, a voltage is applied to the plate electrodes causing the captured labels to emit light. The instrument

measures the intensity of emitted light to provide a quantitative measure of analyte in the sample.

Performance Characteristics:

1. Analytical performance: All results for analytical performance met the sponsor's predetermined acceptance criteria for each study.

   a. Precision/Reproducibility:

   The precision and reproducibility of the assay were calculated by testing five serum samples containing various concentrations of CRP. Each sample was run in duplicate, two runs per day, for 20 days with one assay kit lot at three testing sites (n = 240 replicates per sample). The results are summarized in the two tables below.

Precision Testing Results – All Data

Level	Concentration (mg/L)	Within-run %CV	Total %CV
Level 1	4.49	10.1	12.6
Level 2	8.47	2.9	8.2
Level 3	10.80	2.8	7.3
Level 4	57.18	3.2	7.2
Level 5	214.11	3.3	11.8

Precision Testing Results – Outliers Removed*

Level	Concentration (mg/L)	Within-run %CV	Total %CV
Level 1	4.45	3.0	7.3
Level 2	8.47	2.9	8.2
Level 3	10.81	2.7	7.1
Level 4	57.18	3.2	7.2
Level 5	215.8	3.3	8.3

*5 Outliers (from a total of 1199 measurements) were removed in accordance with CLSI EP05-A3

   b. Linearity/assay reportable range:

   Linearity: Linearity was evaluated according to CLSI guideline EP06-A. "Low" and "High" CRP serum pools were created by mixing individual samples. Materials from the High and Low CRP pools were combined to create a total of eleven (11) serial dilutions. A total of four (4) replicate runs were performed on each dilution sample using a single MSD CRP Assay Kit lot. The results of the regression analysis are summarized as follows:

Test Range (mg/L)	Slope (95% CI)	Intercept (95% CI)	R^2	% Recovery
0.627 — 201	0.942 (0.926 — 0.958)	0.0296 (-0.0389 — 0.0982)	0.997	-8.9% — 0.0%

   The assay is linear from 3 – 160 mg/L.

Hook effect: The assay was tested for prozone or hook effect up to a CRP concentration of 800 mg/L. No prozone effect was observed within the linear range of the assay.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability: The calibrators used to calibrate the assay are traceable to the CRM474 reference material.

Value assignment: A reference lot is created by diluting bulk calibration material. It is assigned using 4 dilutions across the quantitation range; CRM474 is utilized as the calibration standard. Production lots of kit calibrator are created by diluting the bulk calibration material in CRP Diluent to the nominal highest calibration level used in the assay. The concentration of each lot of kit calibrator is assigned using 4 dilutions across the quantitation range, using the reference lot as the calibration standard.

Stability: The real-time stability for un-opened components was performed using multiple kit lots. The results support a kit shelf life of 7 months. Storage temperatures for each kit component are found on the component labels and in the product insert.

d. Detection limit:

Limit of Blank (LoB) was determined by testing one hundred twenty (120) blank replicates created using MSD CRP Diluent without addition of the MSD CRP Calibrator. Samples were run on multiple kit lots and the statistical method for determining LoB for each kit lot was based on whether the data distribution was Non-Gaussian or Gaussian in accordance with CLSI guideline EP17-A2. The LoB was determined to be 0.02 mg/L for all tested kit lots.

Limit of Detection (LoD) was determined by testing one hundred twenty (120) low-level CRP samples created by testing twenty (20) replicates of six (6) low-level serum pools prepared by mixing MSD CRP Calibrator and MSD CRP Diluent in varying proportions. Samples were run on multiple kit lots and the LoD was calculated according to CLSI guideline EP17-A2 to be 0.039, 0.048 and 0.049 mg/L for each of the tested kit lots.

Limit of Quantification (LoQ) was validated by testing eight (8) replicates of six (6) low-level CRP pools that were prepared by mixing the MSD CRP Calibrator and the MSD CRP Diluent in varying proportions close to the lower limit of the reportable range. CLSI guideline EP17-A2 defines LoQ as the lowest concentration of the analyte that can be reported with a Total Error (TE) <20%. The test results support the claimed LoQ of 3 mg/L.

e. Analytical specificity:

Endogenous/Drug Interference: Five serum samples were spiked with potential endogenous interferents or drugs, respectively. The control samples were prepared for each substance/agent by spiking with the same volume of MSD CRP Diluent. Each sample was measured in five replicates across three reagent lots. The percent difference was calculated for each reagent lot by comparing to a corresponding control sample. The average % difference (n=15) for all substances was less than 10%, indicating that interference from the following substances was not significant at the concentration tested.

Potential Interfering Substance	Concentration Tested	Average % Difference	SD of % Difference	Range of % Difference
Unconjugated Bilirubin	32 mg/dL	0.5%	4.4%	-4.3% — 10.8%
Conjugated Bilirubin	5.4 mg/dL	6.6%	6.3%	-0.4% — 20.0%
Hemoglobin	22,200 mg/dL	-6.2%	1.8%	-9.1% — -3.2%
Triglyceride-rich lipoproteins	633 mg/dL	1.9%	5.7%	-6.3% — 12.5%
Rheumatoid Factor	4000 IU/mL	4.0%	8.1%	-10.4% — 16.0%
Human anti-mouse antibodies	500 ng/mL	1.6%	2.7%	-3.8% — 7.4%
Name of Agent	**Concentration Tested**	**Average % Difference**	**SD of % Difference**	**Range of % Difference**
Acetaminophen	1324 µM	1.5%	4.3%	-7.1% — 7.0%
Acetylsalicylic acid	3.62 mM	2.2%	3.2%	-3.2% — 9.3%
Ibuprofen	2425 µM	3.3%	8.2%	-18.0% — 20.3%
Salicylic acid	4.34 mM	-0.6%	5.8%	-16.5% — 6.8%
Methotrexate	2 mmol/L	1.9%	1.6%	-0.5% — 4.8%

f. Assay cut-off:

See the reference range/expected value.

2. Comparison studies:

a. Method comparison with predicate device:

A total of 120 serum samples were tested with the MSD CRP Assay Kit and MESO SECTOR S 700 Instrument and the predicate Roche Diagnostics C-Reactive Protein (Latex) Assay and Roche Diagnostics Cobas Integra 800 Analyzer. Passing-Bablok regression analysis was performed by comparing the results obtained from the MSD system (y) and the predicate (x). The results are summarized below:

N	Range (mg/L)	Slope (95% CI)	Intercept (95% CI)	R-squared
120	3.7-179.0	1.094 (1.077-1.120)	0.088 (-0.548-0.736)	0.988

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity and Clinical Specificity:

Not applicable

b. Other clinical supportive data:

Not applicable

4. Clinical cut-off:

See assay cut-off.

5. Expected values/Reference range:

The reference range in the normal population was verified per CLSI EP28-A3c by testing 120 apparently healthy individuals. Samples reflected a representative adult U.S. population with respect to race, age, and gender. The results showed a median CRP value of 1.01 mg/L; the central 95% interval was 0.100 – 12.9 mg/L.

Proposed Labeling:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

Conclusion:

The information contained in this 510(k) premarket notification has demonstrated that the MSD CRP Assay Kit and MESO SECTOR S 700 Instrument is substantially equivalent to the Roche Diagnostics C-Reactive Protein (Latex) Assay and Roche Diagnostics Cobas Integra 800 Analyzer cleared in K073277.