May 3, 2019

Siemens Healthcare Diagnostics Products GmbH
Christine Perkins
Regulatory Specialist
Emil-von-Behring Str-76
35041 Marburg, Germany

Re: K190879
Trade/Device Name: N Latex FLC kappa, N Latex FLC lambda
Regulation Number: 21 CFR 866.5550
Regulation Name: Immunoglobulin (light chain specific) immunological test system
Regulatory Class: Class II
Product Code: DFH, DEH
Dated: April 3, 2019
Received: April 4, 2019

Dear Christine Perkins:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Doug Jeffery
Acting Deputy Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190879

Device Name
N Latex FLC kappa
N Latex FLC lambda

Indications for Use *(Describe)*

In-vitro diagnostic reagents for the quantitative determination of free light chains (FLC), type kappa or type lambda in human serum and EDTA-plasma. FLC measurements are used as an aid in the diagnosis and monitoring of multiple myeloma (MM) and as an aid in the diagnosis of amyloidosis (AL) in conjunction with other laboratory and clinical findings.
The response category assignment of 'Complete Response' for the monitoring of MM, is reliant upon the combination of clinical history and other tests including protein electrophoresis, immunofixation and bone marrow, imaging and urine assessments.

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 per 21 CFR 807.92
Type of 510(k): Special 510(k)

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: ____K190879_____

1. Submitter

Siemens Healthcare Diagnostics Products GmbH
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35041 Marburg, Germany

Contact Person :	Christine Perkins
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Date of Preparation:	April 03, 2019

2. Device Information

Proprietary Name:	N Latex FLC kappa assay N Latex FLC lambda assay
Common or Usual Name:	Light Chain immunological test system
Product Code :	DFH (kappa) DEH (lambda)
Classification Name:	Immunoglobulin (light chain specific) immunological test system per 21CFR 866.5550
Regulatory Class:	II
510(k) Review Panel:	Clinical Immunology (82)

3. Legally Marketed Unmodified / Predicate Devices

Cleared for use on Siemens' BN Systems under K171742 on November 17, 2017 as an aid in the diagnosis of multiple myeloma (MM) and amyloidosis; cleared under K182098 on November 1, 2018 for monitoring of MM:

Trade Name	Common/Usual Name	Classification	Product Code	Panel	FDA clearance
N Latex FLC kappa	Immunoglobulin (light chain specific) immunological test system	Class II per 21CFR 866.5550	DFH	Immunology (82)	K171742 K182098
N Latex FLC lambda	Immunoglobulin (light chain specific) immunological test system	Class II per 21CFR 866.5550	DEH	Immunology (82)	K171742 K182098

4. Device Description / Test Principle of the Modified Device

The N Latex FLC (free light chain) assays are *in vitro* diagnostic reagents for the quantitative determination of free light chains, type kappa or type lambda, in human serum and EDTA plasma by means of particle-enhanced immunoassay determination. Used in conjunction with other clinical and laboratory findings, FLC measurements are used as an aid in the diagnosis and monitoring of multiple myeloma (MM) and as an aid in the diagnosis of amyloidosis (AL).

Polystyrene particles coated with antibodies to human free light chains, type kappa or lambda, respectively, are agglutinated when mixed with samples containing FLC. A concentration curve is obtained by monitoring agglutination and measuring the increase in turbidity. The actual change in absorbance is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

5. Intended Use / Indications for Use

N Latex FLC kappa and N Latex FLC lambda assays

In-vitro diagnostic reagents for the quantitative determination of free light chains (FLC), type kappa or type lambda in human serum and EDTA-plasma. FLC measurements are used as an aid in the diagnosis and monitoring of multiple myeloma (MM) and as an aid in the diagnosis of amyloidosis (AL) in conjunction with other laboratory and clinical findings.
The response category assignment of 'Complete Response' for the monitoring of MM, is reliant upon the combination of clinical history and other tests including protein electrophoresis, immunofixation and bone marrow, imaging and urine assessments.

N FLC Supplementary Reagent

Supplementary reagent for the immunonephelometric determination of free light chains (FLC), type kappa and type lambda on BN Systems.
Supplementary reagent for the turbidimetric determination of free light chains (FLC), type kappa and type lambda on the Atellica® CH Analyzer.

A mixture of both supplementary reagents is used to suppress interference by rheumatoid factors and human anti-mouse antibodies (HAMA).

6. Special Conditions for Use Statements

For prescription use only.

The result of the FLC kappa or FLC lambda in a given specimen determined with assays and/or instrument platforms from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the FLC kappa or FLC lambda assay used. Values obtained with different assay methods cannot be used interchangeably.

If, in the course of serially monitoring a patient, the assay method used for determining the FLC kappa and FLC lambda levels is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

7. Special instrument requirements:

Atellica® CH Analyzer (K151767)
BN II System (K943997)
BN ProSpec® (K001647)

8. Technological characteristics

Similarities and Differences to the predicate:

A comparison of the similarities and differences between the proposed Atellica® CH N Latex FLC assays versus the BN Systems' N Latex FLC assays (predicates):

Comparison of Technological Characteristics

	Predicate **Siemens Healthcare** **BN Systems** N Latex FLC kappa N Latex FLC lambda (K171742, K182098)	**Siemens Healthcare** **Atellica® CH Analyzer** **Modified Devices** N Latex FLC kappa N Latex FLC lambda
Indications for Use	*In-vitro* diagnostic reagents for the quantitative determination of free light chains (FLC), type kappa or type lambda in human serum and EDTA-plasma by means of particle-enhanced immunonephelometry using the BN Systems. FLC measurements are used as an aid in the diagnosis and monitoring of multiple myeloma (MM) and as an aid in the diagnosis of amyloidosis (AL) in conjunction with other laboratory and clinical findings. The response category assignment of 'Complete Response' for the monitoring of MM, is reliant upon the combination of clinical history and other tests including protein electrophoresis, immunofixation and bone marrow, imaging and urine assessments.	*In-vitro* diagnostic reagents for the quantitative determination of free light chains (FLC), type kappa or type lambda in human serum and EDTA-plasma. FLC measurements are used as an aid in the diagnosis and monitoring of multiple myeloma (MM) and as an aid in the diagnosis of amyloidosis (AL) in conjunction with other laboratory and clinical findings. Same
Sample Type	Human serum and EDTA plasma	Same
Reagent Packaging	3 x 1 mL	Same
Reagent Handling	Bottles placed directly on system	Reagents poured into reagent containers
Units	mg/L	Same
Detection Method	Nephelometry	Turbidimetry
Measurement	Quantitative	Same
Detection Antibody	Monoclonal mouse anti-human FLC kappa Monoclonal mouse anti-antibody FLC lambda	Same
Reagent Composition	Polystyrene particles coated with monoclonal antibodies	Same
Traceability	Internal Reference Plasma Pool	Same

	Predicate **Siemens Healthcare** **BN Systems** N Latex FLC kappa N Latex FLC lambda (K171742, K182098)	**Siemens Healthcare** **Atellica® CH Analyzer** **Modified Devices** N Latex FLC kappa N Latex FLC lambda
Calibrators	One level	Same
Calibration Interval	42 days	Same
Analytical Measuring Range	Typical range: kappa: 3.4 to 110 mg/L lambda: 1.9 to 60 mg/L	kappa: 3.91 to 60 mg/L lambda: 5.47 to 70 mg/L
Reference Interval	kappa: 8.24 to 28.90 mg/L lambda: 9.10 to 32.60 mg/L Ratio: 0.53 to 1.51	Same

The modification of the predicate devices is to add the Atellica® CH Analyzer to the N Latex FLC kappa and lambda assays.

7. Summary of Design Control Activities

A risk analysis was performed with risks identified. Mitigation of risk to acceptable levels was achieved through verification activities summarized below.

7.1 Risk Analysis

Risk analysis was performed according to the ISO14971:2007 standard, Medical Devices – Application of Risk Management to Medical Devices. The change to the N Latex FLC kappa and N Latex FLC lambda assays, previously cleared for use on the BN Systems, is to adapt them for use on the Atellica® CH Analyzer. The reagents used for both systems are identical in composition, packaging and labeling.

Each difference was analyzed, and its effect identified. Severity and probability were estimated by risk class. Risks were mitigated to the degree acceptable.

7.2. Verification Activities

Based on the results of the risk analysis, verification activities were identified, pertinent studies were determined and acceptance criteria established.

The test methods and acceptance criteria used for N Latex FLC kappa and lambda on the Atellica® CH Analyzer are equivalent to those used for the predicate device.

8. Comments on Substantial Equivalency

The reagents for the proposed devices and the cleared devices are identical in composition, labeling and packaging. Comparative testing was performed, and the results obtained demonstrate substantial equivalent performance.

The use of these reagents on another instrument platform with a different measuring technology, i.e., nephelometry versus turbidimetry, does not affect safety and efficacy when used according to the product labeling.

9. Conclusion

The modified devices, N Latex FLC kappa and lambda on the Atellica® CH Analyzer, are substantially equivalent to the predicate devices based on intended use design, and basic scientific principle and performance.

Results from the risk analysis and design control activities with comparative testing support a substantial equivalence decision.