May 2, 2019

Sebia
Karen Anderson
Director of Regulatory and Technical
1705 Corporate Drive, Suite 400
Norcross, Georgia 30093

Re: K190851
Trade/Device Name: HYDRASHIFT 2/4 daratumumab
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system
Regulatory Class: Class II
Product Code: CFF
Dated: March 5, 2019
Received: April 2, 2019

Dear Karen Anderson:

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)*
K190851

Device Name
HYDRASHIFT 2/4 daratumumab

Indications for Use *(Describe)*
HYDRASHIFT 2/4 daratumumab kits are to be used in conjunction with the HYDRAGEL IF kits and the semi-automated HYDRASYS 2 electrophoresis apparatus. HYDRASHIFT 2/4 daratumumab with the HYDRAGEL IF kit are intended for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis. The proteins, separated by electrophoresis on alkaline buffered agarose gels, are incubated with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa (free and bound) and lambda (free and bound) light chains, respectively. After removing the non-reacted proteins, the immunoprecipitates are stained with acid violet. The electrophoregrams are evaluated visually for the presence of specific reactions with the suspect monoclonal proteins. The HYDRASHIFT 2/4 daratumumab kits remove the daratumumab Ig G, Kappa interference and enable the visual evaluation of the presence or absence of monoclonal proteins on the HYDRAGEL IF kits in patients who have received daratumumab therapy.

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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510K SUMMARY (Summary of Safety and Effectiveness)

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

Submitter Name	Sebia, Inc.
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Date Prepared	March 5, 2019
Manufacturing	Sebia Parc Technologique Léonard de Vinci Rue Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex FRANCE Phone: (33) 1 69 89 80 80 Fax: (33) 1 69 89 78 78
Product Name	HYDRASHIFT 2/4 daratumumab
Common Name	Hydrashift daratumumab Serum Immunofixation
Product Regulation No.	21CFR sec. 866.5510
Product Codes	CFF

Device classification and Panel Classification	Class II , Immunology (82)
Establishment Registration No.	8023024
Predicate Devices	The candidate device is a modification of the predicate device. The device name , HYDRASHIFT 2/4 daratumumab, is unchanged from how it was cleared in 510(k) K172195

1. DEVICE DESCRIPTION

HYDRASYS 2 is a semi-automated multi-parameter system for start-to finish agarose gel electrophoresis: application of samples, migration, incubation, drying, staining, destaining and final-stage drying.

Abnormal bands in serum protein electrophoregrams, primarily those in the beta globulin and gamma globulin zones, are always suspected to be monoclonal proteins (M-proteins, paraproteins, monoclonal immunoglobulins) and therefore, an indication of performing an Immunofixation technique to type and confirm the monoclonal gammopathies.

Daratumumab is a human therapeutic Ig G Kappa monoclonal antibody and as such, during the clinical monitoring of patients treated with daratumumab, this antibody simulates a band detected by serum protein electrophoresis and immunofixation in the gamma region. It can simulate an endogenous Ig G Kappa paraprotein.

2. INDICATIONS FOR USE

The HYDRASHIFT 2/4 daratumumab test is intended for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis. The kits are to be used in conjunction with the HYDRAGEL IF kits and the semi-automated HYDRASYS 2 electrophoresis apparatus. The proteins, separated by electrophoresis on alkaline buffered agarose gels, are incubated with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa (free and bound) and lambda (free and bound) light chains, respectively. After removing the non-reacted proteins, the immunoprecipitates are stained with acid violet. The electrophoregrams are evaluated visually for the presence of specific reactions with the suspect monoclonal proteins. The HYDRASHIFT 2/4 daratumumab kits remove the daratumumab Ig G, Kappa interference and enable the visual evaluation of the presence or absence of monoclonal proteins on the HYDRAGEL IF kits in patients who have received daratumumab therapy.

For In Vitro Diagnostic Prescription Use Only.

Note: The intended use of the modified device, as described in its labeling, has not changed as the result of the modification.

3. TECHNOLOGICAL CHARACTERISTICS

The candidate device, HYDRASHIFT 2/4 daratumumab, has been modified from the predicate device with the addition to the package insert labeling as follows:

- Additional to the Anti – daratumumab reagent provided in the kit,
  The anti-daratumumab antiserum is ready to use. It contains anti-daratumumab total immunoglobulins from **Chinese hamster ovary cells (CHO).** For easy identification of the
  antiserum and as an aid in monitoring its application, the antiserum is colored with distinct nonhazardous dye that matches the color of the vial label.

The following tables compare the HYDRASHIFT 2/4 daratumumab with its predicate device, HYDRASHIFT 2/4 daratumumab (K172195)

Table 1: Assay Comparison

Item	HYDRASHIFT 2/4 daratumumab Predicate Device (K172195)	HYDRASHIFT 2/4 daratumumab Candidate/Modified Device
Intended Use	The HYDRASHIFT 2/4 daratumumab test is intended for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis. The kits are to be used in conjunction with the HYDRAGEL IF kits and the semi-automated HYDRASYS 2 electrophoresis apparatus. The proteins, separated by electrophoresis on alkaline buffered agarose gels, are incubated with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa (free and bound) and lambda (free and bound) light chains, respectively. After removing the non-reacted proteins, the immunoprecipitates are stained with acid violet. The electrophoregrams are evaluated visually for the presence of specific reactions with the suspect monoclonal proteins. The HYDRASHIFT 2/4 daratumumab kits remove the daratumumab Ig G, Kappa interference and enable the visual evaluation of the presence or absence of monoclonal proteins on the HYDRAGEL IF kits in patients who have received daratumumab therapy. For In Vitro Diagnostic Prescription Use Only.	Same
Instrumentation	Sebia HYDRASYS 2	Same

Immunofixation (IF) test kits used in conjuction with the HYDRASHIFT 2/4 daratumumab	HYDRAGEL 4 IF Acid violet Standard mask, HYDRAGEL 4 IF Acid violet Dynamic mask.	Same
Scientific Technology	Agarose Gel Electrophoresis	Same
Specimen Type	Serum	Same
Results	Qualitative	Same
Sensitivity/ Lowest detectable daratumumab limit	The detection limit of daratumumab and / or daratumumab / anti-daratumumab antibody complexvisualized is 0.3 g/**L**	Same
Efficiency (Maximum removal of complex)	3.0 g/L	Same
Daratumumab band when treated with HYDRASHIFT daratumumab kit	Removed from gamma zone into alpha zone	Same
Stability of the anti-daratumumab reagent Stability 2 to 8ºC	2 years	Same
daratumumab Control	daratumumab control (K172195)	Same

Table 2: Assay Comparison, Labelled Performance Characteristics

Item	HYDRASHIFT 2/4 daratumumab Predicate Device (K172195)	HYDRASHIFT 2/4 daratumumab Candidate/Modified Device
Package Insert Labeling	The anti-daratumumab antiserum is ready to use. It contains **murine anti-daratumumab** total immunoglobulins. For easy identification of the antiserum and as an aid in monitoring its application, the antiserum is colored with distinct nonhazardous dye that matches the color of the vial label.	The anti-daratumumab antiserum is ready to use. It contains anti-daratumumab total immunoglobulins from **Chinese hamster ovary cells.** For easy identification of the antiserum and as an aid in monitoring its application, the antiserum is colored with distinct nonhazardous dye that matches the color of the vial label

Table 3: Kit and Components

HYDRASHIFT 2/4 daratumumab (K172195)			HYDRASHIFT 2/4 daratumumab		
Items	PN 4639 (20 TESTS)	PN 4640 (40 TESTS)		PN 4639 (20 TESTS)	PN 4640 (40 TESTS)
Anti-daratumumab mouse antiserum (ready to use)	1 vial, 0.4 mL	1 vial, 0.85mL	Anti-daratumumab Chinese hamster ovary cells antiserum (ready to use)	1 vial, 0.4 mL	1 vial, 0.85 mL
Sample diluent (ready to use)	1 vial, 2.2 mL	1 vial, 2.2 mL	Sample diluent (ready to use)	Same	Same
Green applicators	1 pack of 10	2 pack of 10	Green applicators	Same	Same

4. Performance Data:
To address the modifications the following studies were conducted to validated the performance of the modified anti-daratumumab (CHO).

4.1 Concordance
Human serum samples of (9 negative samples without monoclonals), (21 daratumumab treated patient samples), (21 daratumumab spiked samples) were compared between the predicate (anti-daratumumab murine) and modified device (anti-daratumumab chinesse hamster ovary cells).
The samples demonstrated 100% concordance.

4.2 Sensitivity and Efficiency
Three serum samples (2 normal serum samples and 1 serum with a IgG Kappa monoclonal) were used in the study. Samples were mixed by adding different concentrations of daratumumab over a concentration range of 0.1 to 3.0 g/L.
The detection limit (sensitivity) of the daratumumab complex at the alpha-1 zone of the G kappa tracks was visualized at 0.3 g/L the same as the predicate device.
The efficiency of the shift of the daratumumab complex to the alpha-1 zone is 3.0 g/L the same as the predicate.

4.3 Stability of the anti-daratumumab
The stability of the anti-daratumumab (CHO) was tested at 2-8ºC in real time and accelerated studies using two lots of anti-daratumumab. Some studies are still on going.
The shelf life is 2 years at 2-8ºC the same as the predicate.

5. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision. The differences between the predicate and candidate device do not impact the indications for use or technical performance of the assay.