May 8, 2018

Ventana Medical Systems, Inc.
Jeffrey M. Catania, Ph.D.
Regulatory Affairs Director
1910 E. Innovation Park Dr.
Tucson, Arizona 87555

Re: K172471
Trade/Device Name: VENTANA CD30 (Ber-H2) Assay
Regulation Number: 21 CFR 866.5550
Regulation Name: Immunoglobulin (light chain specific) immunological test system
Regulatory Class: Class II
Product Code: DEH
Dated: April 5, 2018
Received: April 6, 2018

Dear Dr. Jeffrey Catania:

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,

Donna M. Roscoe -S
2018.05.08 15:17:03 -04'00'

For Reena Philip, Ph.D.
Director
Division of Molecular Genetics and Pathology
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)*
K172471

Device Name
VENTANA CD30 (Ber-H2) Assay

Indications for Use *(Describe)*
The VENTANA CD30 (Ber-H2) Assay is intended for laboratory use in the qualitative detection of the CD30 protein in formalin-fixed, paraffin-embedded tissue stained with a VENTANA BenchMark ULTRA instrument and OptiView DAB IHC Detection Kit. CD30 positive staining may aid in the identification of classical Hodgkin lymphoma (cHL), anaplastic large cell lymphoma (ALCL) and cutaneous T-cell lymphoma (CTCL). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.

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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510(k) Summary

Submitter: Ventana Medical Systems, Inc.
1910 E Innovation Park Drive
Tucson, AZ 85755
(520) 887-2155
Contact: Jeffrey Catania
Date Prepared: 04-May-2018
510(K): K172471

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

This 510(k) has not yet been assigned a number.

Device Name	Proprietary Name: VENTANA CD30 (Ber-H2) Assay
	Classification: 21CFR866.5550, Immunoglobulin (light chain specific) immunological test system.
	Product Code: DEH
Predicate Device	DAKO Corporation's Monoclonal Mouse Anti-Human Ki-1antigen, CD30, Clone Ber-H2
	K965022
Device Description	The VENTANA CD30 (Ber-H2) Assay consists of the primary CD30 (Ber-H2) antibody, detection reagents and an instrument (BenchMark ULTRA automated staining instrument). The VENTANA CD30 (Ber-H2) Assay is a mouse monoclonal antibody (IgG1, kappa) directed against CD30. CD30 antigen is expressed in mononuclear Hodgkin's cells and multinucleated Reed Sternberg cells of Hodgkin Lymphoma as well as on anaplastic large cell lymphomas. This antibody variably produces membranous, cytoplasmic, and Golgi staining of both lymphoma cells and of scattered large activated B and T cells in lymph nodes, spleen, tonsil, and thymus. The OptiView DAB IHC Detection Kit is an indirect, biotin-free system for detecting mouse IgG, mouse IgM, and rabbit primary antibodies. This kit is intended to detect antigens by IHC in sections of formalin-fixed, paraffin-embedded (FFPE) and frozen tissues that are stained on the BenchMark ULTRA instrument (note: the VENTANA CD30 (Ber-H2) Assay will not be recommended for use in frozen tissue). The OptiView DAB IHC Detection Kit produces a visible dark brown precipitate (3, 3'-Diaminobenzidine) via a horseradish peroxidase (HRP) enzymatic reaction at the antigen site. The Pathologist evaluates the brown precipitate using Bright-field microscopy.

Intended Use	The VENTANA CD30 (Ber-H2) Assay is intended for laboratory use in the qualitative detection of the CD30 protein in formalin-fixed, paraffin-embedded tissue stained with a VENTANA BenchMark ULTRA instrument and OptiView DAB IHC Detection Kit. CD30 positive staining results may aid in the identification of classical Hodgkin lymphoma (cHL), anaplastic large cell lymphoma (ALCL) and cutaneous T-cell lymphoma (CTCL). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
Summary of the new and predicate devices	VENTANA CD30 (Ber-H2) Assay consists of the primary CD30 (Ber-H2) antibody (mouse monoclonal), detection reagents and an automated staining instrument (BenchMark ULTRA). It is intended for the qualitative detection of CD30 by immunohistochemistry in formalin fixed, paraffin embedded human tissue. The CD30 antigen is expressed in mononuclear Hodgkin's cells and multinucleated Reed Sternberg cells of Hodgkin Lymphoma as well as on anaplastic large cell lymphomas. This antibody variably produces membranous, cytoplasmic, and Golgi staining of both lymphoma cells and may be used to aid in the identification of classical Hodgkin lymphoma and anaplastic large cell lymphoma. The VENTANA CD30 (Ber-H2) Assay has been compared to a predicate device, 'Monoclonal Mouse Anti-Human Ki-1antigen, CD30, Clone Ber-H2' developed by DAKO Corporation, which reports a similar indication and staining pattern. The predicate was granted 510(k) clearance by FDA in 1992 (K965022). The intended use of the predicate, as reported in the 1992 510(k), states that, "Monoclonal mouse anti-human Ki-1 antigen, CD30, Clone Ber-H2 (Ber-H2), may be used as one member of a panel of antibodies to aid in the differential diagnosis of large anaplastic cells of undetermined origin. This antibody stains cell membranes of most cases of anaplastic large cell lymphomas (ALCL), often called Ki-1 lymphomas. It also stains cell membranes and/or cytoplasm of most Hodgkin's lymphomas …. The staining pattern is most often described as strong membranous and weaker cytoplasmic, specifically paranuclear dot-positivity of the Golgi region..." The results of testing have been compared between VENTANA CD30 (Ber-H2) Assay and the DAKO K965022 device through a premethod comparison study. The results of the study show a 91.0% (517-568) overall percent agreement rate between three readers and a 92.8% (739/796) overall agreement rate between four readers. It has been concluded that the VENTANA CD30 (Ber-H2) Assay and the predicate DAKO K965022 device are substantially equivalent.

Non-clinical performance data	Non-clinical (analytical) performance testing has been conducted to demonstrate performance characteristics of VENTANA CD30 (Ber-H2) Assay. Method Comparison studies have demonstrated substantial equivalence to predicate device (Dako K965022).

Comparison of VENTANA CD30 (Ber-H2) to Predicate Device, DAKO CD30 (Ber-H2)		
Parameter	Predicate device	Proposed device
Proprietary Name	DAKO Corporation's Monoclonal Mouse Anti-Human Ki-1antigen, CD30, Clone Ber-H2 – K965022	VENTANA CD30 (Ber-H2) Assay
FDA Classification	Class II, non-Exempt	Class II, non-Exempt
Intended Use	Monoclonal mouse anti-human Ki-1 antigen, CD30, Clone Ber-H2 (Ber-H2), may be used as one member of a panel of antibodies to aid in the differential diagnosis of large anaplastic cells of undetermined origin. This antibody stains cell membranes of most cases of anaplastic large cell lymphomas (ALCL), often called Ki-1 lymphomas. It also stains cell membranes and/or cytoplasm of most Hodgkin's lymphomas. Ber-H2 is a valuable aid in the assessment of cutaneous lymphoid infiltrates, particularly when large atypical cells are present. Most nonhematolymphoid neoplasms are negative with Ber-H2, although there are several significant exceptions. Membrane positivity is seen with embryonal carcinomas, and weak, diffuse cytoplasmic positivity is seen in pancreatic and salivary gland carcinomas. The staining pattern is most often described as strong membranous and weaker cytoplasmic, specifically paranuclear dot-positivity of the Golgi region. The weak, diffuse cytoplasmic staining is considered to be unexpected, non-specific labeling. It may be reduced or removed by changing the protease pretreatment of the paraffin sections and/or further dilution of the Ber-H2 antibody.	The VENTANA CD30 (Ber-H2) Assay is intended for laboratory use in the qualitative detection of the CD30 protein in formalin-fixed, paraffin-embedded tissue stained with a VENTANA BenchMark ULTRA instrument. CD30 positive staining results may aid in the identification of classical Hodgkin lymphoma (cHL) and anaplastic large cell lymphoma (ALCL). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This antibody is intended for *in vitro* diagnostic (IVD) use.

Comparison of VENTANA CD30 (Ber-H2) to Predicate Device, DAKO CD30 (Ber-H2)		
Parameter	Predicate device	Proposed device
Proprietary Name	DAKO Corporation's Monoclonal Mouse Anti-Human Ki-1antigen, CD30, Clone Ber-H2 – K965022	VENTANA CD30 (Ber-H2) Assay
Sample	Acetone fixed, frozen and formalin or B5 fixed, paraffin-embedded tissues	Formalin fixed, paraffin embedded human tissue
Assay Method	IHC	IHC
Target	CD30	CD30
Assay Format	Automated	Automated
Detection System	Direct	Direct
Visualization	Interpretation by light microscopy	Interpretation by light microscopy
Intended Use Population	Hodgkin's Lymphoma and Anaplastic Large Cell Lymphoma	Hodgkin's Lymphoma and Anaplastic Large Cell Lymphoma
Qualitative or Quantitative	Qualitative	Qualitative
Conclusion	VENTANA CD30 (Ber-H2) Assay is substantially equivalent to Dako's 510(k) cleared cd30 Ber-H2 clone in relevant characteristics and performance; any differences will not adversely affect safety and efficacy.	