February 3, 2023

Beckman Coulter, Inc.
Kate Oelberg
Senior Staff Quality and Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, MN 55318

Re: K223679
Trade/Device Name: Access AMH
Regulation Number: 21 CFR 862.1092
Regulation Name: Anti-Mullerian Hormone Test System
Regulatory Class: Class II
Product Code: PQO
Dated: December 8, 2022
Received: December 8, 2022

Dear Kate Oelberg:

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,

Paula Caposino -S

Digitally signed by Paula Caposino -S
Date: 2023.02.03 17:08:40 -05'00'

Paula Caposino, Ph.D.
Acting Deputy Director
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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)*
K223679

Device Name
Access AMH

Indications for Use *(Describe)*
The Access AMH assay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of anti-Müllerian hormone (AMH) levels in human serum and lithium heparin plasma using the Access Immunoassay Systems as an aid in the assessment of ovarian reserve in women presenting to fertility clinics. This system is intended to distinguish between women presenting with AFC (antral follicle count) values > 15 (high ovarian reserve) and women with AFC values ≤ 15 (normal or diminished ovarian reserve). The Access AMH is intended to be used in conjunction with other clinical and laboratory findings such as antral follicle count, before starting fertility therapy. The Access AMH is not intended to be used for monitoring of women undergoing controlled ovarian stimulation in an Assisted Reproduction Technology program.

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

510(k) Number k223679 Date Prepared: February 3, 2023

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

The assigned 510(k) number is k223679.

Submitted By:
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Device Name:
Common Name: Anti-Müllerian hormone test system
Trade Name: Access AMH
Classification Name: Anti-Müllerian hormone test system
Classification Regulation: (21 CFR 862.1092)

Predicate Device:
Device Name: Access AMH
510(k) Numbers: k170524

Device Description

The Access Anti-Mullerian Hormone Assay, Access Anti-Mullerian Hormone Calibrators, and the Access Immunoassay analyzers comprise the DxI 9000 Access Immunoassay System for the quantitative determination of Anti-Mullerian Hormone levels in human serum and lithium heparin plasma using the DxI 9000 Access Immunoassay system.

Intended Use

The Access AMH assay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of anti-Mullerian hormone (AMH) levels in human serum and lithium heparin plasma using the Access Immunoassay Systems as an aid in the assessment of ovarian reserve in women presenting to fertility clinics. This system is intended to distinguish between women presenting with AFC (antral follicle count) values > 15 (high ovarian reserve) and women with AFC values ≤ 15 (normal or diminished ovarian reserve). The Access AMH is intended to be used in conjunction with other clinical and laboratory findings such as antral follicle count, before starting fertility therapy. The Access AMH is not intended to be used for monitoring of women undergoing controlled ovarian stimulation in an Assisted Reproduction Technology program.

Comparison of Technological Characteristics to the Predicate

Parameter	Access AMH Assay on Access 2 Immunoassay System Predicate – k170524	Access AMH Assay on DxI 9000 Access Immunoassay Analyzer
Intended use	The Access AMH assay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of anti-Müllerian hormone (AMH) levels in human serum and lithium heparin plasma using the Access Immunoassay Systems as an aid in the assessment of ovarian reserve in women presenting to fertility clinics. This system is intended to	Same

Parameter	Access AMH Assay on Access 2 Immunoassay System Predicate – k170524	Access AMH Assay on DxI 9000 Access Immunoassay Analyzer
	distinguish between women presenting with AFC (antral follicle count) values >15 (high ovarian reserve) and women with AFC values ≤15 (normal or diminished ovarian reserve). The Access AMH is intended to be used in conjunction with other clinical and laboratory findings such as antral follicle count, before starting fertility therapy. The Access AMH is not intended to be used for monitoring of women undergoing controlled ovarian stimulation in an Assisted Reproduction Technology program.	
Analyte Measured	Anti-Müllerian hormone (AMH) levels in human serum and lithium heparin plasma	Same
Technology	Two-site immunoenzymatic (sandwich) assay	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum or plasma	Same
Reagent Pack formulation and packaging	Access Reagent Pack formulation and packaging.	Same
Measuring Range	0.08-24 ng/mL (0.57-171 pmol/L).	Same
Reagent Stability	Unopened at 2° to 10°C until stated expiration date	Same
Substrate	Access Substrate	Lumi-Phos PRO Substrate
Instrument	Access 2 Immunoassay system	DxI 9000 Access Immunoassay Analyzer

Summary of Studies

Method Comparison: The results of the Access AMH assay on the DxI 9000 are comparable to those of the Access AMH assay on Access 2. Further, the estimated bias at concentrations corresponding to reference limits defined on the predicate system suggest that such values have not changed appreciably on the DxI 9000 system.

N	Concentration Range* (ng/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
126	0.11 - 22	1.02	1.00 - 1.03	0.011	-0.013 - 0.067	1.00

*Range is Access 2 values

Imprecision: The within-laboratory (total) % CV ranged from 2.2% to 5.4%, for AMH concentrations > 0.16 ng/mL. Access AMH Advanced assay meets total error and bias acceptance criteria with maximum Total Error (TE) of 16%.

ng/mL			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	88	0.29	0.010	3.6	0.006	2.0	0.006	2.0	0.013	4.6
Sample 2	88	0.80	0.030	3.7	0.000	0.0	0.000	0.0	0.030	3.7
Sample 3	88	1.0	0.03	3.0	0.02	2.1	0.03	3.0	0.05	4.8
Sample 4	88	2.4	0.11	4.5	0.00	0.0	0.05	2.0	0.12	5.0
Sample 5	88	5.1	0.18	3.4	0.03	0.7	0.09	1.7	0.20	3.9
Sample 6	88	6.9	0.19	2.8	0.00	0.0	0.16	2.3	0.25	3.6
Sample 7	88	13	0.4	3.1	0.3	1.9	0.3	2.6	0.6	4.5
Sample 8	88	16	0.7	4.4	0.0	0.0	0.5	3.1	0.8	5.4
Sample 9	88	19	0.5	2.6	0.3	1.8	0.3	1.4	0.6	3.4

Linearity: The results of this study met the acceptance criterion and indicate that the Access AMH assay is linear on the DxI 9000 Immunoassay System throughout the analytical measuring interval (0.08 - 24 ng/mL (0.57 - 171 pmol/L).

Limit of Blank (LoB): The LoB for AMH was determined to be 0.001 ng/mL on the DxI 9000 Immunoassay System. The results of this study demonstrate that the AMH assay met the acceptance criterion of ≤ 0.01 ng/mL.

Limit of Detection (LoD): The LoD estimate for the AMH assay is 0.002 ng/mL on the DxI 9000 Immunoassay System. The results of this study demonstrate that the AMH assay met the acceptance criterion of ≤ 0.02 ng/mL on the DxI 9000 Access Immunoassay System.

Limit of Quantitation (LoQ): The results provided demonstrate the 20% CV LoQ estimate for the Access AMH assay is 0.003 ng/mL (0.02 pmol/L). The results provided demonstrate the LoQ at 20% within-laboratory (total) CV estimate of the Access AMH assay to be ≤ 0.08 ng/mL (0.57 pmol/L).

Reproducibility: The study shows that the Access AMH assay meets design input requirements for reproducibility on DxI 9000 with an SD ≤ 0.042 ng/mL for values ≤ 0.16 ng/mL and CV ≤ 13.0% for values > 0.16 ng/mL.

Conclusion: The information provided in this submission demonstrates that the proposed new device is substantially equivalent to the predicate device.