April 26, 2023

Beckman Coulter, Inc
Neha Desai
Staff Quality and Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K222996
Trade/Device Name: Access PCT
Regulation Number: 21 CFR 866.3215
Regulation Name: Device To Detect And Measure Non-Microbial Analyte(s) In Human Clinical Specimens To Aid In Assessment Of Patients With Suspected Sepsis
Regulatory Class: Class II
Product Code: PTF
Dated: September 27, 2022
Received: September 28, 2022

Dear Neha Desai:

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,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222996

Device Name
Access PCT

Indications for Use *(Describe)*
The Access PCT assay is a paramagnetic, chemiluminescent immunoassay for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay Systems. Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock.

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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Immunodiagnostic Development Center
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a)(1).

The assigned 510(k) number is K222996

Submitted By:

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Date Prepared:

February 17th, 2023

Device Name:

Proprietary / Trade Name: Access PCT Reagent
Common Name: Procalcitonin Immunoassay
Classification Name: Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis
Classification Regulation: 21 CFR 866.3215
Classification Product Code: PTF

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Predicate Device:

The Access PCT Assay/Calibrators claims substantial equivalence to previously cleared Access PCT Assay FDA 510(k) Number K192271.

Device Description:

The Access PCT assay is a paramagnetic, chemiluminescent immunoassay for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay Systems. Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock.A description of the reagent pack is provided below.

- R1a: Dynabeads* paramagnetic particles coated with mouse anti-human Procalcitonin monoclonal antibody in a TRIS buffer with surfactant, protein (bovine), ≤ 0.1% sodium azide, and 0.1% ProClin**300
- R1b: 0.10 N Sodium Hydroxide
- R1c: MOPS Buffer with surfactant and protein (bovine, murine), ≤ 0.1 % sodium azide, and 0.1% ProClin 300
- R1d: Rat anti-Procalcitonin recombinant alkaline phosphatase conjugate in a MOPS buffer with surfactant and protein (bovine, murine, recombinant),
  ≤ 0.1% sodium azide, and 0.1% ProClin 300
  *Dynabead® is a registered trademark of Dynal A.S., Oslo, Norway
  **ProClin™ is a trademark of The Dow Chemical Company (“Dow”) or an affiliate company of Dow.

Intended Use:

The Access PCT assay is a paramagnetic, chemiluminescent immunoassay for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay Systems. Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock.

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Comparison of Technological Characteristics to the Predicate (Assay)

System Attribute/Characteristic	Predicate Access PCT on Access 2 Immunoassay System (K192271)	Access PCT on Dxl 9000 Access Immunoassay Analyzer
Intended Use/ Indications for Use	The Access PCT assay is a paramagnetic particle, chemiluminescent immunoassay for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay System. Measurement of PCT in conjunction with other laboratory findings and clinical assessment aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock.	Same
Analyte Measured	Procalcitonin (PCT)	Same
Technology	Two-step sandwich	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Human Serum or Plasma (LiHep and EDTA)	Same
Measuring Range	0.05 to 100 ng/mL	Same
LoB	≤ 0.005 ng/mL	Same
LoD	≤ 0.01 ng/mL	Same
LoQ	20% CV at ≤ 0.02 ng/mL	Same
Hook	No hook effect up to procalcitonin concentrations of 5,000 ng/mL	Same
Stability	Stable at 2 to 10°C for 42 days after initial use	Same
Reagent Pack materials	Mouse anti-human procalcitonin monoclonal antibody	Same
Assay Duration	Approximately 20 minutes	Approximately 14 minutes

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System Attribute/Characteristic	Predicate Access PCT on Access 2 Immunoassay System (K192271)	Access PCT on DxI 9000 Access Immunoassay Analyzer
Sample Volume	35 µL	15 µL
Instrument	Access 2 Immunoassay system	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos PRO substrate

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Summary of Studies

Method Comparison: The results of the method comparison study met the acceptance criteria of $R^2 \geq 0.95$ and slope 1.00 ± 0.10 and supports the equivalence of the Access PCT assay on DxI 9000 to the Access PCT assay on Access 2 Instrument. The bias data supports the reference intervals defined on the Access 2 system have not changed appreciably on the DxI 9000 system.

Method Concordance: The percentage of concordance between the Access 2 Immunoassay System and the DxI 9000 Access Immunoassay Analyzer for the cut-offs of 0.5 and 2.0 ng/mL were 100.0% and 98.3%, respectively.

Imprecision: The Within Laboratory (total) % CV was between 2.2% and 6.1% for PCT concentrations ≥ 0.150 ng/mL. The Within laboratory (total) SD was between 0.006 – 0.008 for PCT concentrations < 0.150 ng/mL.
The study met the acceptance criteria of SD ≤ 0.012 ng/mL for values < 0.150 ng/mL and CV ≤ 8.0% for values ≥ 0.150 ng/mL.

The Within Run (total) % CV was between 1.9% and 4.7% for PCT concentrations ≥ 0.150 ng/mL. The Within Run (total) SD was between 0.004 – 0.007 for PCT concentrations < 0.150 ng/mL.
The study met the acceptance criteria of SD ≤ 0.009 ng/mL for values < 0.150 ng/mL and CV ≤ 6.0% for values ≥ 0.150 ng/mL.

Linearity: The study shows that acceptance criteria was met for detectable non-linearity within ± 0.012 ng/mL for values ≤ 0.150 ng/mL and ± 10% for values > 0.150 ng/mL.

Limit of Blank (LoB): The data demonstrated the LoB estimate of the PCT assay is 0.002 ng/mL, which met the acceptance criteria of ≤ 0.005 ng/mL.

Limit of Detection (LoD): The data demonstrated the LoD estimate of PCT is 0.003 ng/mL which met the acceptance criteria of ≤ 0.01 ng/mL.

Limit of Quantitation (LoQ): The results demonstrated the 20% CV LoQ estimate for the Access PCT assay to be 0.002 ng/mL which meets the acceptance criteria of less than or equal to 0.02 ng/mL
The maximum observed LoQ estimate for Access PCT assay on the DxI 9000 immunoassay System is less than the reported LoD value (0.003ng/mL). Following the CLSI EP17-A2 recommendation that the LoQ must be greater than or equal to LoD, the LoQ value is reported as 0.003 ng/mL to align with LoD.

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Conclusion:

The information provided in this submission supports a substantial equivalence determination, and therefore 510(k) premarket notification clearance of the PCT assay on DxI 9000 Access Immunoassay Analyzer.

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