September 29, 2023

Abbott Laboratories
Lisa Kelly
Associate Director Regulatory Affairs
100 Abbott Park Road
Dept.09AA, Building CP1
Abbott Park, Illinois 60064

Re: K232669
Trade/Device Name: TBI
Regulation Number: 21 CFR 866.5830
Regulation Name: Brain trauma assessment test
Regulatory Class: Class II
Product Code: QAT
Dated: August 31, 2023
Received: September 1, 2023

Dear Lisa Kelly:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology 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.

Submission Number *(if known)*

K232669

Device Name

TBI

Indications for Use *(Describe)*

The TBI test is a panel of in vitro diagnostic chemiluminescent microparticle immunoassays (CMIA) used for the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in human plasma and serum and provides a semi-quantitative interpretation of test results derived from these measurements using the ARCHITECT i1000SR System.
The interpretation of test results is used, in conjunction with other clinical information, to aid in the evaluation of patients, 18 years of age or older, presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15) within 12 hours of injury, to assist in determining the need for a CT (computed tomography) scan of the head. A negative test result is associated with the absence of acute intracranial lesions visualized on a head CT scan.
The TBI test is intended for use in clinical laboratory settings by healthcare professionals.

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

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

I. Applicant Name

Date summary prepared: September 29, 2023

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100 Abbott Park Road
Abbott Park, IL 60064

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II. Device Name

TBI

Reagents

Trade Name: Glial fibrillary acidic protein (GFAP)
Ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1)
Device Classification: Class II (Special controls)
Classification Name: Brain trauma assessment test
Governing Regulation: 21 CFR § 866.5830
Product Code: QAT

III. Predicate Device

TBI K223602

IV. Description of Device

The TBI test is a panel of in vitro diagnostic quantitative measurements of GFAP and UCH-L1 and provides a semi-quantitative interpretation of GFAP and UCH-L1 in human plasma and serum.

GFAP:

This assay is an automated, two-step immunoassay for the quantitative measurement of GFAP in human plasma and serum using chemiluminescent microparticle immunoassay (CMIA) technology.

Sample, anti-GFAP coated paramagnetic microparticles, and assay specific diluent are combined and incubated. The GFAP present in the sample binds to the anti-GFAP coated microparticles. The mixture is washed. Anti-GFAP acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of GFAP in the sample and the RLU detected by the system optics.

UCH-L1:

This assay is an automated, two-step immunoassay for the quantitative measurement of UCH-L1 in human plasma and serum using CMIA technology.

Sample, anti-UCH-L1 coated paramagnetic microparticles, and assay specific diluent are combined and incubated. The UCH-L1 present in the sample binds to the anti-UCH-L1 coated microparticles. The mixture is washed. Anti-UCH-L1 acridinium-labeled conjugate is added to create a reaction mixture and incubated.

Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as an RLU. There is a direct relationship between the amount of UCH-L1 in the sample and the RLU detected by the system optics.

Interpretation of Results

The assay cutoffs were established to be 35.0 pg/mL (35.0 ng/L) for GFAP and 400.0 pg/mL (400.0 ng/L) for UCH-L1.

The GFAP and UCH-L1 results are reported separately and the software provides a TBI interpretation relative to the respective cutoff values as shown in the following table.

Specification for Constituent Assay Results	TBI Result	TBI Interpretation
GFAP and UCH-L1 below (<) cutoff	0	Negative
GFAP and/or UCH-L1 above (≥) cutoff	1	Positive

The following table provides a detailed summary of the TBI interpretation based on potential results.

GFAP Assay Result (Relative to Cutoff of 35.0 pg/mL [35.0 ng/L])*	UCH-L1 Assay Result (Relative to Cutoff of 400.0 pg/mL [400.0 ng/L])*	TBI Interpretation**
Below	Below	Negative
Below	Above	Positive
Above	Below	Positive
Above	Above	Positive
No result	Below	Not reportable***
No result	Above	Positive***
Below	No result	Not reportable***
Above	No result	Positive***
No result	No result	Not reportable***

* Above means greater than or equal to the cutoff. Below means less than the cutoff.

** The GFAP and UCH-L1 results can be found on the Result Details screen under Constituent Information on the User Interface.

*** An automated TBI interpretation will not be reported for specimens without a result for GFAP and/or UCH-L1. The GFAP and/or UCH-L1 assay(s) may be retested if needed to obtain a result and a manual TBI interpretation may be required. The TBI interpretation for a specimen is considered positive if the result for either constituent assay (GFAP or UCH-L1) is greater than or equal to the cutoff and no result is obtained for the other assay. The TBI interpretation for a specimen is not reportable if the result for either constituent assay is less than the cutoff and no result is obtained for the other assay.

In the case of a flagged ">" or "<" result for either assay, the TBI interpretation should be evaluated manually. A result flagged ">" should be considered above the cutoff and a result flagged "<" should be considered below the cutoff.

V. Intended Use of the Device

The TBI test is a panel of *in vitro* diagnostic chemiluminescent microparticle immunoassays (CMIA) used for the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in human plasma and serum and provides a semi-quantitative interpretation of test results derived from these measurements using the ARCHITECT i1000SR System.

The interpretation of test results is used, in conjunction with other clinical information, to aid in the evaluation of patients, 18 years of age or older, presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15) within 12 hours of injury, to assist in determining the need for a CT (computed tomography) scan of the head. A negative test result is associated with the absence of acute intracranial lesions visualized on a head CT scan.

The TBI test is intended for use in clinical laboratory settings by healthcare professionals.

VI. Comparison of Technological Characteristics

The similarities and differences between the subject device and the predicate device are presented in the following table.

Characteristics	Cleared Predicate Device: TBI for Alinity i (K223602)	Subject Device: TBI for ARCHITECT
General Device Characteristic Similarities		
Intended Use and Indications for Use	The TBI test is a panel of *in vitro* diagnostic chemiluminescent microparticle immunoassays (CMIA) used for the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in human plasma and serum and provides a semi-quantitative interpretation of test results derived from these measurements using the Alinity i system. The interpretation of test results is used, in conjunction with other clinical information, to aid in the evaluation of patients, 18 years of age or older, presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15) within 12 hours of injury, to assist in determining the need for a CT (computed tomography) scan of the head. A negative test result is associated with the absence of acute intracranial lesions visualized on a head CT scan. The TBI test is intended for use in clinical laboratory settings by healthcare professionals.	The TBI test is a panel of *in vitro* diagnostic chemiluminescent microparticle immunoassays (CMIA) used for the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in human plasma and serum and provides a semi-quantitative interpretation of test results derived from these measurements using the ARCHITECT i1000SR System. The interpretation of test results is used, in conjunction with other clinical information, to aid in the evaluation of patients, 18 years of age or older, presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15) within 12 hours of injury, to assist in determining the need for a CT (computed tomography) scan of the head. A negative test result is associated with the absence of acute intracranial lesions visualized on a head CT scan. The TBI test is intended for use in clinical laboratory settings by healthcare professionals.
Intended Use Setting	Clinical Laboratory	Same
Measurands	GFAP and UCH-L1	Same
Specimen Type	Plasma and serum	Same
Assay Technology	CMIA	Same

Characteristics	Cleared Predicate Device: TBI for Alinity i (K223602)	Subject Device: TBI for ARCHITECT
Reportable Result	Quantitative results for GFAP and UCH-L1 and semi-quantitative interpretation for TBI	Same
Calibrators	GFAP: 6 levels UCH-L1: 6 levels	Same
Controls	GFAP: 3 levels (25.0, 500.0, and 30000.0 pg/mL) UCH-L1: 3 levels (250.0, 2000.0, and 15000.0 pg/mL)	Same
Assay Format	Two separate test kits – one for GFAP and one for UCH-L1	Same
Sample Volume	GFAP kit: 200 µL UCH-L1 kit: 150 µL	Same
Reportable Interval (pg/mL, ng/L)	Analytical Measuring Interval: GFAP: 6.1 – 42,000.0 UCH-L1: 26.3 – 25,000.0 Reportable Interval: GFAP: 3.2 - 42,000.0 UCH-L1: 18.3 - 25,000.0	Same
GFAP Cutoff	35.0 pg/mL (35.0 ng/L)	Same
UCH-L1 Cutoff	400.0 pg/mL (400.0 ng/L)	Same
Reagent formulation	GFAP Reagent Kit • Microparticles: Anti-GFAP (rabbit, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizer. Minimum concentration: 0.05 % solids. Preservative: ProClin 300. • Conjugate: Anti-GFAP (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.2 mg/L. Preservative: ProClin 300. • Assay Specific Diluent: TRIS buffer with protein (bovine) stabilizer. Preservative: ProClin 300.	Same

Characteristics	Cleared Predicate Device: TBI for Alinity i (K223602)	Subject Device: TBI for ARCHITECT
Reagent formulation (continued)	<u>UCH-L1 Reagent Kit</u> • Microparticles: Anti-UCH-L1 (mouse, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizer. Minimum concentration: 0.05% solids. Preservative: sodium azide. • Conjugate: Anti-UCH-L1 (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.2 mg/L. Preservative: ProClin 300. • Assay Specific Diluent: TRIS buffer with protein (bovine) stabilizer. Preservative: sodium azide.	Same
General Device Characteristic Differences		
Instrument Platform	Alinity i system	ARCHITECT i1000SR System
Reagent Packaging Configuration	<u>GFAP Reagent Kit</u> 2 Cartridges x 100 Tests • 1 cartridge (7.1 mL) Microparticles • 1 cartridge (6.4 mL) Conjugate • 1 cartridge (6.4 mL) Assay Specific Diluent <u>UCH-L1 Reagent Kit</u> 2 Cartridges x 100 Tests • 1 cartridge (7.1 mL) Microparticles • 1 cartridge (12.5 mL) Conjugate • 1 cartridge (10.5 mL) Assay Specific Diluent	<u>GFAP Reagent Kit</u> 100 Tests • 1 bottle (7.4 mL) Microparticles • 1 bottle (6.7 mL) Conjugate • 1 bottle (6.7 mL) Assay Specific Diluent <u>UCH-L1 Reagent Kit</u> 100 Tests • 1 bottle (7.4 mL) Microparticles • 1 bottle (12.0 mL) Conjugate • 1 bottle (10.9 mL) Assay Specific Diluent

VII. Performance Summary:

The TBI test using the GFAP assay and UCH-L1 assay, evaluated on the ARCHITECT i1000SR System, met the pre-defined product requirements for all characteristics evaluated in the verification studies.

Verification Activity	**TBI on ARCHITECT i1000SR**
GFAP 20-Day Precision	2.2 to 6.2 %CV for samples with GFAP concentrations from 20.4 to 37,098.8 pg/mL
UCH-L1 20-Day Precision	2.2 to 4.5 %CV for samples with UCH-L1 concentrations from 187.6 to 19,645.0 pg/mL
GFAP Reproducibility	2.7 to 6.0 %CV for samples with GFAP concentrations from 23.6 to 34,087.5 pg/mL 1.30 pg/mL SD for sample with GFAP concentration 19.1 pg/mL
UCH-L1 Reproducibility	2.4 to 3.9 %CV for samples with UCH-L1 concentrations from 193.0 to 20,363.2
GFAP LoB, LoD, LoQ	LoB – 2.0 pg/mL LoD – 3.2 pg/mL LoQ – 6.1 pg/mL
UCH-L1 LoB, LoD, LoQ	LoB – 9.2 pg/mL LoD – 18.3 pg/mL LoQ – 26.3 pg/mL
GFAP Linearity	GFAP 6.1 to 42,000.0 pg/mL
UCH-L1 Linearity	UCH-L1 26.3 to 25,000.0 pg/mL
Sample Onboard	2 hours
Reagent Onboard/ Calibration Curve Storage	30 days

Method

Comparison Summary

Studies were performed based on guidance from CLSI EP09c, 3rd ed. using the Passing-Bablok regression method.

Assay	N	ARCHITECT i1000SR (pg/mL)		Alinity i (pg/mL)		Correlation Coefficient (r)		Intercept		Slope	
		Min	Max	Min	Max	R	95% CI	Estimate	95% CI	Estimate	95% CI
GFAP	123	7.9	32359.2	6.5	32548.6	1.00	(1.00,1.00)	-0.6	(-1.1, -0.3)	1.03	(1.02,1.05)
UCH-L1	123	48.7	23763.7	51.5	24127.7	1.00	(1.00,1.00)	-6.0	(-7.9, -4.0)	1.06	(1.05,1.07)

VIII. Conclusion

The results presented in this Special 510(k) demonstrate that the performance of the subject device (TBI on the ARCHITECT i1000SR) is substantially equivalent to the performance of the predicate device (TBI on the Alinity i system, K2223602).