August 10, 2023

Abbott Laboratories
Dominic Tunzi
Regulatory Project Manager
100 Abbott Park Road
Abbott Park, Illinois 60064

Re: K222850
Trade/Device Name: HAVAb IgG II
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A Virus (HAV) Serological Assays
Regulatory Class: Class II
Product Code: LOL
Dated: September 19, 2022
Received: September 21, 2022

Dear Dominic Tunzi:

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,

Maria I. Garcia -S

Maria Garcia, Ph.D.
Assistant Director
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)*
K222850

Device Name
HAVAb IgG II

Indications for Use *(Describe)*
The HAVAb IgG II assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human adult and pediatric (4 through 21 years) serum (collected in serum and serum separator tubes) and plasma (collected in sodium heparin, lithium heparin, lithium heparin separator, dipotassium EDTA, and tripotassium EDTA tubes) from patients with signs and symptoms or at risk for hepatitis A on the Alinity i system.
The HAVAb IgG II assay is used to determine the immune status of individuals to hepatitis A virus (HAV) infection.
Warning: This assay has not been cleared for use in screening blood, plasma, or tissue donors. This assay cannot be used for the diagnosis of acute HAV infection.
Assay performance characteristics have not been established when the HAVAb IgG II assay is used in conjunction with other hepatitis assays.

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. 510(k) Number

K222850

II. Applicant Name

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Date Summary Prepared: August 9, 2023

III. Device Name

HAVAb IgG II

Reagent

Trade Name: HAVAb IgG II Reagent Kit
Device Classification: Class II
Classification Name: Hepatitis A virus (HAV) serological assays
Governing Regulation: 21 CFR § 866.3310
Code: LOL

Calibrator

Trade Name: HAVAb IgG II Calibrator
Device Classification: Class II
Classification Name: Clinical Chemistry Test Systems: Calibrator
Governing Regulation: 21 CFR § 862.1150
Code: JIS

Controls

Trade Name: HAVAb IgG II Controls
Device Classification: Class II
Classification Name: Assayed quality control material for clinical microbiology assays
Governing Regulation: 21 CFR § 866.3920
Code: QCH

IV. Predicate Device

Abbott Laboratories: ARCHITECT HAVAB-G (-K113704)

V. Description of Device

A. Reagents

The kit configuration of the HAVAb IgG II reagent kit is described below.

Tests per cartridge	100
Number of cartridges per kit	2
Tests per kit	200
Microparticles	6.6 mL
Conjugate	26.5 mL
Assay Diluent	10.4 mL

Microparticles:	HAV (human) coated microparticles in MOPS / potassium chloride buffer. Minimum concentration: 0.08% solids. Preservative: ProClin 300.
Conjugate:	Anti-human IgG (mouse, monoclonal) acridinium-labeled conjugate in MES / sodium chloride buffer with protein (bovine) stabilizer and surfactants. Minimum concentration: 0.01 µg/mL. Preservatives: ProClin 300 and ProClin 950.
Assay Diluent:	Assay diluent containing protein (goat, mouse, and bovine) stabilizers in TRIS buffer and surfactant. Preservatives: ProClin 300 and ProClin 950.

B. Calibrator

The HAVAb IgG II Calibrator is described below.

Calibrator 1 contains recalcified human plasma reactive for IgG antibody to hepatitis A virus (IgG anti-HAV). Preservatives: ProClin 300 and sodium azide.

The target concentration for the calibrator is provided in the following table.

Calibrator	Quantity	Color	IgG Anti-HAV Concentration (mIU/mL)
Calibrator 1	1 x 3.0 mL	Green[a]	50.0

[a] Dye: Green (Acid Yellow No. 23 and Acid Blue No. 9)

The HAVAb IgG II Calibrator is traceable to the World Health Organization (WHO) 2nd International Standard for Anti-hepatitis A, Immunoglobulin, Human (NIBSC Code: 97/646).

C. Controls

The HAVAb IgG II Controls are described below.

- The negative control contains recalcified anti-HAV negative human plasma with protein (bovine) stabilizer.
- The positive control contains recalcified human plasma reactive for IgG anti-HAV.

Preservatives: ProClin 300 and sodium azide.

The target ranges for the controls are provided in the table below. The ranges may be used for individual replicate control specifications on the Alinity i system.

Control	Quantity	Color	IgG Anti-HAV Range (S/CO)
Negative Control	3 x 3.0 mL	Natural	≤ 0.56
Positive Control	3 x 3.0 mL	Blue[b]	1.03 – 3.53

[b] Dye: Acid Blue No. 9

The HAVAb IgG II positive control is traceable to the WHO 2nd International Standard for Anti-hepatitis A, Immunoglobulin, Human (NIBSC code: 97/646).

D. Biological Principles of the Procedure

This assay is an automated, two-step immunoassay for the qualitative detection of IgG anti-HAV in human adult and pediatric serum and plasma from patients with signs and symptoms or at risk for hepatitis using chemiluminescent microparticle immunoassay (CMIA) technology.

Sample, HAV (human) coated paramagnetic microparticles, and assay diluent are combined and incubated. The IgG anti-HAV present in the sample binds to the HAV (human) coated microparticles. The mixture is washed. Anti-human IgG 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 IgG anti-HAV in the sample and the RLU detected by the system optics.

The presence or absence of IgG anti-HAV in the sample is determined by comparing the chemiluminescent RLU in the reaction to the cutoff RLU determined from an active calibration.

VI. Intended Use of the Device

The HAVAb IgG II assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human adult and pediatric (4 through 21 years) serum (collected in serum and serum separator tubes) and plasma (collected in sodium heparin, lithium heparin, lithium heparin separator, dipotassium EDTA, and tripotassium EDTA tubes) from patients with signs and symptoms or at risk for hepatitis A on the Alinity i system.

The HAVAb IgG II assay is used to determine the immune status of individuals to hepatitis A virus (HAV) infection.

Warning: This assay has not been cleared for use in screening blood, plasma, or tissue donors. This assay cannot be used for the diagnosis of acute HAV infection.

Assay performance characteristics have not been established when the HAVAb IgG II assay is used in conjunction with other hepatitis assays.

VII. Comparison of Technological Characteristics

The HAVAb IgG II assay (subject device) is an automated immunoassay for the qualitative detection of IgG anti-HAV in human adult and pediatric serum and plasma from patients with signs and symptoms or at risk for hepatitis using CMIA technology on the Alinity i system.

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

Comparison of Subject Device (HAVAb IgG II) to Predicate Device (ARCHITECT HAVAB-G)

Similarities and Differences Between Subject & Predicate Device		
	Subject Device: HAVAb IgG II	**Predicate Device: ARCHITECT HAVAB-G (k113704)**
General Device Characteristic Similarities		
Intended Use and Indications for Use	The HAVAb IgG II assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human adult and pediatric (4 through 21 years) serum (collected in serum and serum separator tubes) and plasma (collected in sodium heparin, lithium heparin, lithium heparin separator, dipotassium EDTA, and tripotassium EDTA tubes) from patients with signs and symptoms or at risk for hepatitis A on the Alinity i system. The HAVAb IgG II assay is used to determine the immune status of individuals to hepatitis A virus (HAV) infection. Warning: This assay has not been cleared for use in screening blood, plasma, or tissue donors. This assay cannot be used for the diagnosis of acute HAV infection. Assay performance characteristics have not been established when the HAVAb IgG II assay is used in conjunction with other hepatitis assays.	The ARCHITECT HAVAB-G assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human adult and pediatric serum from patients with signs and symptoms or at risk for hepatitis. The ARCHITECT HAVAB-G assay is used to determine the immune status of individuals to hepatitis A virus infection. **Warning: This assay has not been FDA cleared or approved for the screening of blood or plasma donors. This assay cannot be used for the diagnosis of acute HAV infection.** Assay performance characteristics have not been established when the ARCHITECT HAVAB-G assay is used in conjunction with other hepatitis assays.
Methodology	Chemiluminescent Microparticle Immunoassay	Chemiluminescent Microparticle Immunoassay
Antigen Used	HAV (Strain pHM175)	HAV (Strain pHM175)
Interpretation of Results	Nonreactive: < 1.00 S/CO Reactive: ≥ 1.00 S/CO	Nonreactive: < 1.00 S/CO Reactive: ≥ 1.00 S/CO
Calibrator(s)	1 Calibrator	1 Calibrator
Control(s)	2 (Negative and Positive)	2 (Negative and Positive)
Within-Laboratory Precision	• 0.011 – 0.045 SD (for samples < 1.00 S/CO) • 2.5 – 5.8 %CV (for samples ≥ 1.00 S/CO)	• 0.029 – 0.050 SD (for samples < 1.00 S/CO) • 3.2 – 4.1 %CV (for samples ≥ 1.00 S/CO)

Similarities and Differences Between Subject & Predicate Device		
	Subject Device: **HAVAb IgG II**	**Predicate Device:** **ARCHITECT HAVAB-G (k113704)**
Reproducibility	• 0.046 – 0.053 SD (for samples < 1.00 S/CO) • 4.7 – 5.2 %CV (for samples ≥ 1.00 S/CO)	• 0.023 – 0.116 SD (for samples < 1.00 S/CO) • 4.6 – 10.8 %CV (for samples ≥ 1.00 S/CO)
General Device Characteristic Differences		
Type of Specimen	Serum and Plasma	Serum
Platform	Alinity i system	ARCHITECT i System
Components	Microparticles – HAV (human) coated microparticles in MOPS / potassium chloride buffer. Minimum concentration: 0.08% solids. Preservative: ProClin 300. Conjugate – Anti-human IgG (mouse, monoclonal) acridinium-labeled conjugate in MES / sodium chloride buffer with protein (bovine) stabilizer and surfactants. Minimum concentration: 0.01 µg/mL. Preservatives: ProClin 300 and ProClin 950. Assay Diluent – Assay diluent containing protein (goat, mouse, and bovine) stabilizers in TRIS buffer and surfactant. Preservatives: ProClin 300 and ProClin 950.	Microparticles – HAV (human) coated microparticles in TRIS buffer. Minimum concentration: 0.08% solids. Preservatives: ProClin 300 and antimicrobial agents. Conjugate – Anti-human IgG (mouse monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.01 µg/mL. Preservatives: sodium azide and antimicrobial agents. Assay Diluent – Protein (goat) stabilizer in TRIS buffer. Preservatives: ProClin 300 and antimicrobial agents.

VIII. Summary of Nonclinical Performance

A. Within-Laboratory Precision (20-Day)

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 2 lots of the HAVAb IgG II reagents, 2 lots of the HAVAb IgG II Calibrator, 1 lot of the HAVAb IgG II Controls, and 2 instruments. Two controls and 2 human serum panels were tested in a minimum of 2 replicates twice per day on 20 days on 4 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot are paired with 1 instrument. The performance from a representative combination is shown in the following table.

Sample	n	Mean (S/CO)	Within-Run (Repeatability)		Within-Laboratory[a]	
			SD	%CV	SD (Range[b])	%CV (Range[b])
High Negative Panel 1	80	0.71	0.025	NA	0.028 (0.026-0.045)	NA
Low Positive Panel 2	80	1.25	0.040	3.2	0.040 (0.036-0.078)	3.2 (2.9-5.8)
Negative Control	80	0.09	0.011	NA	0.015 (0.011-0.035)	NA
Positive Control	80	2.19	0.053	2.4	0.063 (0.055-0.090)	2.9 (2.5-4.0)

NA = Not applicable

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across 4 reagent lot/calibrator lot/instrument combinations.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

B. Analytical Specificity

Potentially Interfering Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.* Each substance was tested at 2 levels of the analyte (approximately 0.80 S/CO and 1.20 S/CO).

No significant interference (interference ≤ +0.10 S/CO for 0.80 S/CO samples and ≥ -10% for 1.20 S/CO samples) was observed at the following concentrations.

No Significant Interference		
	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
Bilirubin (Conjugated)	40 mg/dL	475 µmol/L
Bilirubin (Unconjugated)	40 mg/dL	684 µmol/L
Biotin	3600 ng/mL	–
Hemoglobin	1000 mg/dL	10 g/L
Total Protein	15 g/dL	150 g/L
Triglycerides	1500 mg/dL	16.94 mmol/L

Other Specimen Conditions or Disease States

The HAVAb IgG II assay was evaluated for potential interference using specimens from individuals with medical conditions unrelated to HAV. All specimens tested nonreactive for IgG anti-HAV as determined by a comparator assay (ARCHITECT HAVAB-G). A total of 251 specimens from 21 different categories were evaluated; 241 specimens (96.02%) were nonreactive and 10 specimens (3.98%) were reactive by the HAVAb IgG II assay.

* Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry.* 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

Category	n	HAVAb IgG II (on Alinity i)	
		Reactive	**Nonreactive**
Anti-cytomegalovirus (anti-CMV)	15	1	14
Anti-Epstein-Barr virus (anti-EBV)	11	0	11
Anti-*Escherichia coli (*anti-*E coli)*	4	1	3
Anti-hepatitis B virus (anti-HBV) (*i.e.*, anti-HBc, anti-HBs, and HBsAg)	24	2	22
Anti-hepatitis C virus (anti-HCV)	13	0	13
Anti-mumps virus	12	0	12
Anti-nuclear antibodies (ANA)	13	0	13
Anti-rubeola (measles) virus	14	0	14
Anti-*Toxoplasma gondii* (anti-*T gondii)*	20	2	18
Anti-varicella zoster virus (anti-VZV)	12	0	12
Human anti-mouse antibodies (HAMA)	9	0	9
Hemodialysis patients	2	1	1
Hepatitis (noninfectious; chronic or acute toxic)	10	0	10
Heterophile antibodies (nonspecific)	5	0	5
Hyper IgG (monoclonal)	14	2	12
Hyper IgM (monoclonal)	6	0	6
Hyper IgM (polyclonal)	3	0	3
Influenza vaccine recipients	12	0	12
Lupus	10	0	10
Multiparous pregnant women (all trimesters)	32	1	31
Rheumatoid factor (RF)	10	0	10
Total	**251**	**10**	**241**

IX. Summary of Clinical Performance

A. Expected Values

Studies were performed with the HAVAb IgG II assay on the Alinity i instrument that included a total of 519 specimens from apparently healthy individuals, 250 specimens from individuals at increased risk of HAV infection, 499 specimens from individuals with signs and symptoms of hepatitis infection, and 105 specimens from the pediatric population.

The specimens from the apparently healthy population were collected from multiple sites in Texas, Wisconsin, and New York. The specimens from adults at increased risk of HAV infection were collected in California, Colorado, Florida, Illinois, Massachusetts, North Carolina, and Texas. The specimens from adults with signs and symptoms of hepatitis infection were collected in California, Colorado, Florida, Illinois, Massachusetts, and Texas. The specimens from the pediatric population were collected in the US (California and Massachusetts) and Belgium. The distribution of reactive and nonreactive results are presented in the table below.

	Apparently Healthy						
	Adults		**Pediatrics**				
	High Prevalence Area(s) for HAV	**Low Prevalence Area(s) for HAV**	**High Prevalence Area(s) for HAV**	**Low Prevalence Area(s) for HAV**	**Increased Risk of HAV Infection**	**Signs and Symptoms of Hepatitis Infection**	**Pediatric Population**
Reactive (%)	34.46	24.87	13.33	13.33	49.19	60.17	86.67
Nonreactive (%)	65.54	75.13	86.67	86.67	50.81	39.83	13.33

In addition, 4 of the 250 specimens collected from individuals at increased risk of HAV infection and 17 of the 499 specimens from individuals with signs and symptoms of hepatitis infection were from pediatric subjects. Of the 21 specimens, 9.52% were reactive and 90.48% were nonreactive.

B. System Reproducibility

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted at each of 3 testing sites using 3 lots of the HAVAb IgG II reagents, 2 lots of the HAVAb IgG II Calibrator, 2 lots of the HAVAb IgG II Controls, and 1 instrument. Two controls and 2 human serum panels were tested in replicates of 4 at 2 separate times per day on 5 different days.

Sample	n	Mean (S/CO)	Repeatability		Within-Laboratory[a]		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV
High Negative Panel A	360	0.66	0.037	NA	0.042	NA	0.053	NA
Low Positive Panel B	360	1.32	0.044	3.4	0.056	4.3	0.069	5.2
Negative Control	360	0.11	0.039	NA	0.042	NA	0.046	NA
Positive Control	360	2.26	0.066	2.9	0.088	3.9	0.106	4.7

[a] Includes repeatability (within-run), between-run, and between-day variability.

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

C. Percent Agreement

A prospective multi-center study was conducted to evaluate the ability of the HAVAb IgG II assay to detect IgG anti-HAV in specimens from individuals at increased risk of HAV infection, individuals with signs and symptoms of hepatitis infection, and of the pediatric population. HAVAb IgG II results on the Alinity i system were compared to the results from the ARCHITECT HAVAB-G assay.

Individuals at Increased Risk of HAV Infection

The percent agreement for specimens from individuals at increased risk of HAV infection (n=250) is summarized in the following table.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

Individuals at Increased Risk of HAV Infection		
	ARCHITECT HAVAB-G	
HAVAb IgG II (on Alinity i)	**Reactive**	**Nonreactive**
Reactive	119	2
Nonreactive	4	125

PPA = 96.75% (119/123), 95% CI (91.94%, 98.73%)

NPA = 98.43% (125/127), 95% CI (94.44%, 99.57%)

Individuals with Signs and Symptoms of Hepatitis Infection

The percent agreement for specimens from individuals with signs and symptoms of hepatitis infection (n=499) is summarized in the following table.

Individuals with Signs and Symptoms of Hepatitis Infection		
	ARCHITECT HAVAB-G	
HAVAb IgG II (on Alinity i)	**Reactive**	**Nonreactive**
Reactive	290	2
Nonreactive	14	193

PPA = 95.39% (290/304), 95% CI (92.42%, 97.24%)

NPA = 98.97% (193/195), 95% CI (96.34%, 99.72%)

Pediatric Population

The percent agreement for specimens from the pediatric population (n=105) is summarized in the following table.

Pediatric Population		
	ARCHITECT HAVAB-G	
HAVAb IgG II (on Alinity i)	**Reactive**	**Nonreactive**
Reactive	90	1
Nonreactive	0	14

PPA = 100.00% (90/90), 95% CI (95.91%, 100.00%)

NPA = 93.33% (14/15), 95% CI (70.18%, 98.81%)

X. Conclusion Drawn from Nonclinical Laboratory Studies and Clinical Performance

The results presented in this 510(k) premarket notification demonstrate that the performance of the subject device, HAVAb IgG II, is substantially equivalent to the predicate device, ARCHITECT HAVAB-G (K113704).