June 25, 2020

Horiba ABX SAS
Caroline Ferrer
Regulatory Affairs Manager
Parc Euromedecine, Rue du Caducee BP7290
Montpellier Cedex 4, 34184France

Re: K192028
Trade/Device Name: Yumizen C1200 CRP
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCK
Dated: July 25, 2019
Received: July 26, 2019

Dear Caroline Ferrer:

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,

Ying (Katelin) Mao, Ph.D.
Acting Chief
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192028

Device Name
Yumizen C1200 CRP

Indications for Use *(Describe)*
Yumizen C1200 CRP reagent is intended for the quantitative in vitro diagnostic determination of the C-reactive protein in human serum and lithium heparin plasma based on an immunoturbidimetric assay. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues and for evaluation of infections, tissue injury and inflammatory disorders. This test should be used in conjunction with other laboratory and clinical findings.

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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SECTION 007 : 510(k) Summary of K192028

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.

1- **Date of Summary**
Date submitted :25th June, 2020

2- **Company**

HORIBA ABX SAS
HORIBA MEDICAL
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
France

3- **Contact person**

Contact Person: Caroline Ferrer (caroline.ferrer@horiba.com)
Telephone: + (33) 4 67 14 1843
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4- **Product Name**
Yumizen C1200 CRP (1300023877)

5- **Device Name and Classification**

- **Intended use**

The devices involved by the 510(k) submission file are the following:

- **Classification and Description**

Device's names	Intended Use
Yumizen C1200 CRP	**Yumizen C1200 CRP** reagent is intended for the quantitative *in vitro* diagnostic determination of the C-reactive protein in human serum and lithium heparin plasma based on an immunoturbidimetric assay. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues and for evaluation of infections, tissue injury and inflammatory disorders. This test should be used in conjunction with other laboratory and clinical findings.

Trade/Proprietary Name:	Yumizen C1200 CRP
Device Class:	Class II / 510(k) required
Classification Name:	§866.5270: C-reactive protein immunological test system
Product Code:	DCK
Panel:	Immunology (82)

- In this submission, HORIBA Medical presents Yumizen C1200 CRP with the Conventional application.

- Predicate: K142993 : QuickRead go CRP on QuickRead go CRP Analyzer / Orion Diagnostica, Oy

- Comparator : K051564 : CRP reagent model : CRP LATEX REAGENT OSR6199 on Olympus AU400 Clinical Chemistry Analyzer / BECKMAN COULTER

- This submission allows to evaluate the functionality of the Yumizen C1200 analyzer for immunology analytes (ie.immunoturbidimetry).

6- Substantial Equivalence Information

The following tables show the similarities and differences and demonstrates substantial equivalence between the candidate device and its predicate device identified below.

a. Predicate Device Name and 510(k) number

Candidate device	Predicate device	Predicate Manufacturer	Predicate 510(k) number
Yumizen C1200 CRP	QuickRead go CRP	Orion Diagnostica, Oy	K142993

The following tables show the similarities and differences and demonstrates substantial equivalence between the candidate device and its predicate device identified below.

b. Yumizen C1200 CRP

Conventional method

i. Comparison with predicate Device : Similarities

Device & Predicate Device(s) :	Predicate K142993	Candidate K192028
Device Trade Name	QuikRead Go CRP	Yumizen C1200 CRP (1300023877)
Intended Use	The QuikRead go CRP test is an immunoturbidimetric assay for the in vitro quantitative determination of C-reactive protein (CRP) in K2-EDTA and lithium heparin whole blood, K2-EDTA and lithium heparin plasma and in serum samples. The test is carried out by means of the QuikRead go instrument. Measurement of C-reactive protein aids in the evaluation of injury to body tissues, and infection and inflammatory disorders. The instrument and assay are for use by trained professionals in the clinical laboratory. For in vitro diagnostic use only. Not for point-of-care use.	**Yumizen C1200 CRP** reagent is intended for the quantitative *in vitro* diagnostic determination of the C-reactive protein in human serum and lithium heparin plasma based on an immunoturbidimetric assay. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues and for evaluation of infections, tissue injury and inflammatory disorders. This test should be used in conjunction with other laboratory and clinical findings.
Technology	Immunoturbidimetry	Same
Assay Type	Quantitative	Same
Analyte	C-reactive protein	Same
Product Code	DCK	Same
Reference Range	< 5 mg/L*	Same

*20 to 60 years

ii. Comparison with predicate Device: Differences

Device & Predicate Device(s) :	Predicate K142993	Candidate K192028
Device Trade Name	QuikRead Go CRP	Yumizen C1200 CRP (1300023877)
Instrument	QuikRead go Analyzer	Yumizen C1200 Clinical chemistry Analyzer
Test	Microparticles	Latex particles
Antibody	Anti-human CRP F(ab)2 fragment	Rabbit anti-CRP antibodies
Sample Type	serum, plasma (Li-Heparin, K2-EDTA), whole blood (Li-heparin, K2-EDTA)	Serum, lithium heparin plasma
Analytical Measuring Range	5 to 200 mg/L: serum and plasma 5 to150 mg/L: whole blood	5 to 160 mg/L
Traceability	ERM-DA 474	IRMM/ERM-DA472/IFCC
Control	Control 1: ~30 mg/L Control 2: ~70 mg/L	Control 1: ~15 mg/L Control 2: ~80 mg/L

7- Special Control/Guidance Document Referenced

a. Standards Followed

The following standards & FDA guidance documents have been used to support this submission:

CLSI Guidelines:

- **CLSI EP05-A3:**Evaluation of Precision of Quantitative Measurement Procedures– Third Edition - October 2014

- **CLSI EP17-A2:** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures – Second Edition - June 2012
- **CLSI EP06-A:** Evaluation of the Linearity of Quantitative measurement Procedures A Statistical Approach – First Edition – April 2003
- **CLSI C28-A3:** Defining, Establishing, and Verifying Reference Intervals in the Clinical laboratory- Third Edition – November 2008
- **CLSI EP25-A** : Evaluation of Stability of In Vitro Diagnostic reagents- First Edition- September 2009

b. FDA Guidances Followed

- Guidance for Industry and FDA Staff : Review Criteria for Assessment of C-Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP Assays) – Document issued on : September 22, 2005

c. References Cited

- Valtec guideline (Vassault et al., Ann. Biol. Clin., 1986, (44), 686-745

8- Device Description

- **Method**

Yumizen C1200 CRP (Licensed for USP6, 248, 597/ USP6, 828, 158 and equivalent patents in other countries) is a latex-enhanced immunoturbidimetric assay developed to accurately measure CRP levels in serum and plasma samples for conventional CRP ranges.
When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of CRP in the sample.
The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

- **Reagent : composition and Description**

Reagents
Yumizen C1200 CRP is ready-to-use.

Reagent 1:
Buffer solution: Glycine buffer solution
Reagent 2:

Latex suspension: 0.20% w/v suspension of latex particles sensitized with anti-CRP antibodies (rabbit)

After measurements are taken, reagent cassettes should remain in the refrigerated tray.
■ Care should be taken not to interchange the caps with others cassettes.
■ Reagents with different lot numbers should not be interchanged or mixed.

This submission consists of the Yumizen C1200 CRP (1300023877) reagent for serum and plasma testing for Yumizen C1200 reagent CRP, the submission includes the controls Yumizen C1200 Level 1 Protein Control (1300023944) and Yumizen C1200 Level 2 Protein Control (1300023945) for use on Yumizen C1200 Analyzer. The submission for Yumizen C1200 reagent CRP also includes the corresponding calibrator Yumizen C1200 CRP Cal (1300023899) for use on Yumizen C1200 Analyzer.

9- Analytical Performance Characteristics

9.1 Measuring Range

- **LOQ**

The limit of detection and quantitation was determined according to the CLSI guideline EP17-A2.

Description of Test Procedure/Method
A range of low concentrations samples has been assayed following this conditions:

- Two reagents lots
- One instrument system
- Five days
- Five samples
- Two run, four replicates per run per sample (for each reagent lot, each day)
- 1 technician

Sample selection: Samples come from dilution of individual serum samples by commercial depleted serum.

- **Linearity**

The reagent linearity was determined according to CLSI guideline EP06-A.

Description:
The linearity is evaluated using a range of samples, at different concentrations covering the desirable range, extended in the lowest and the highest ends.
Each level has been assayed 3 times.
The highest concentration sample used for this study is a pooled human sera sample spike with CRP stock solution.

The limit of quantitation and the linearity studies showed that claimed measuring range is appropriate.

- Results :

	Limit of detection	Limit of quantitation	Linearity Evaluated	Measuring range
Serum	0.23 mg/L	5 mg/L	9.42 to 150.78 mg/L.	5.0 to 160 mg/L,
Serum Post-dilution	NA	NA	up to 737.40 mg/L	until 800 mg/L

With Linearity – range 9.42 – 150.78 mg/L

Range (mg/L)	**Slope (95%CI)**	**Intercept (95% CI)**	**R^2**
9.42 – 150.78	1.026 (1.005 – 1.047)	-1.33 (-3.23 – +0.58)	0.9972

9.2 Accuracy and Precision

Standards Followed
CLSI document, EP5-A3

- Total Precision : 20x2x2

Study materials :
- Yumizen C1200 Level 1 Protein Control
- Yumizen C1200 Level 2 Protein Control
- Pooled human sera, anonymous remnants of human sera specimens collected from routine clinical laboratory.

Description of Test Procedure/Method
This evaluation was performed using 3 analyzers using 3 reagent lot.

The dedicated controls and 5 specimens covering the measuring range (low, medium and high) were tested in duplicate for 20 days, two series per day.

Within run : CV limits, for the low, middle and high level are respectively 9.0 %, 4.5 % and 3.8 %.
Total precision: CV limits, for the low, middle and high level are respectively 12.0 %, 6.0 % and 5.0 %.

Sample	N	Mean (mg/L)	Within-run		Between-run		Between-day		Between-instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	240	5.06	0.042	0.8	0.053	1.0	0.125	2.5	0.037	0.7	0.147	2.9
2	240	9.79	0.075	0.8	0.075	0.8	0.083	0.8	0.052	0.5	0.144	1.5
3	240	27.61	0.208	0.8	0.388	1.4	0.629	2.3	0.000	0.0	0.768	2.8
4	240	65.33	0.597	0.9	0.582	0.9	0.921	1.4	0.303	0.5	1.279	2.0
5	240	141.27	2.546	1.8	0.000	0.0	2.372	1.7	0.976	0.7	3.614	2.6
Control 1	240	16.57	0.130	0.8	0.235	1.4	0.338	2.0	0.000	0.0	0.432	2.6
Control 2	240	74.88	0.637	0.9	0.888	1.2	0.847	1.1	0.567	0.8	1.494	2.0

The results are within the specifications.

- Instrument variability : 3x5x2x3

Study materials: - Yumizen C1200 Level 1 Protein Control
- Yumizen C1200 Level 2 Protein Control
- Pooled human sera, anonymous remnants of human sera specimens collected from routine clinical laboratory

Description of Test Procedure/Method
The experimental is:

- One reagent lot
- Three instruments systems
- 2 controls and 6 samples tested in triplicate for 5 days, two series per day.
- Calibrations are done at the beginning of the study.

Within Run : CV limits, for the low, middle and high level are respectively 9.0 %, 4.5 % and 3.8 %
Total Precision : CV limits, for the low, middle and high level are respectively 12.0 %, 6.0 % and 5.0 %.

Sample	N	Mean (mg/L)	Within-day		Between-day		Within-instrument		Between-instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	90	5.16	0.055	1.1	0.066	1.3	0.086	1.7	0.104	2.0	0.135	2.6
2	90	9.80	0.085	0.9	0.049	0.5	0.098	1.0	0.094	1.0	0.136	1.4
3	90	25.44	0.268	1.1	0.174	0.7	0.319	1.3	0.653	2.6	0.727	2.9
4	90	71.28	0.944	1.3	1.078	1.5	1.433	2.0	0.884	1.2	1.683	2.4
5	90	94.77	1.227	1.3	0.714	0.8	1.420	1.5	1.052	1.1	1.767	1.9
6	90	139.02	2.080	1.5	0.815	0.6	2.234	1.6	1.839	1.3	2.893	2.1
Control 1	90	14.32	0.162	1.1	0.196	1.4	0.254	1.8	0.320	2.2	0.409	2.9
Control 2	90	71.50	1.024	1.4	1.244	1.7	1.611	2.3	1.232	1.7	2.028	2.8

The results are within the specifications.

- Lot to Lot variability : 3x5x2x3

Study materials: - Yumizen C1200 Level 1 Protein Control
- Yumizen C1200 Level 2 Protein Control
- Pooled human sera, anonymous remnants of human sera specimens collected from routine clinical laboratory

Description of Test Procedure/Method
The experimental is:
- Three reagent lot
- One instrument system
- 2 controls and 6 samples tested in triplicate for 5 days, two series per day.
- Calibrations are done at the beginning of the study.

Within Run : CV limits, for the low, middle and high level are respectively 9.0 %, 4.5 % and 3.8 % for serum
Total Precision : CV limits, for the low, middle and high level are respectively 12.0 %, 6.0 % and 5.0 % for serum.

Sample	N	Mean (mg/L)	Within-run		Between-day		Within-lot		Between-lot		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	90	5.21	0.056	1.1	0.064	1.2	0.085	1.6	0.080	1.5	0.117	2.2
2	90	9.74	0.119	1.2	0.019	0.2	0.120	1.2	0.178	1.8	0.215	2.2
3	90	24.70	0.273	1.1	0.207	0.8	0.343	1.4	0.273	1.1	0.438	1.8
4	90	71.70	0.701	1.0	1.143	1.6	1.341	1.9	1.493	2.1	2.007	2.8
5	90	95.65	0.939	1.0	1.236	1.3	1.552	1.6	0.603	0.6	1.665	1.7
6	90	139.38	1.833	1.3	1.588	1.1	2.425	1.7	1.177	0.8	2.696	1.9
Control 1	90	13.95	0.126	0.9	0.187	1.3	0.226	1.6	0.112	0.8	0.252	1.8
Control 2	90	72.78	0.974	1.3	1.025	1.4	1.414	1.9	1.268	1.7	1.899	2.6

The results are within the specifications.

9.3 Interferences

The Interferences were determined according to the CLSI guideline EP07-A2.

Study of the interferences from the hemolysis, triglycerides, icteria (total and direct bilirubin) samples and from Ascorbic Acid, Acetylsalicylic Acid, Ibuprofen, Acetaminophen, rheumatoid factor (RF), Erythromycin, Gentamycin, Ampicillin, Prednisone, Methotrexate, Etanercept, Simvastatin and Omeprazole on the CRP assay with the Yumizen C1200 CRP reagent on the Yumizen C1200.

Description of Test Procedure/Method
Study materials: Pooled Human sera. Substances were added to the base sera at two different CRP concentrations (normal and high). The base sera with each substance was then serially diluted with the same base sera for which same volume of diluent was added instead of substance to adjust CRP concentration.

The acceptable bias is defined at +/-10% of the value without interfering substances.

These data in the following table represent the highest values for which no interferences higher than 10% have been observed.

Serum		
Hemoglobin	290 µmol/L	500 mg/dL
Triglycerides	5.77 mmol/l	504 mg/dL
Total Bilirubin	607 µmol/	35.53 mg/dL
Direct Bilirubin	393 µmol/L	22.97 mg/dL
Ascorbic Acid	340 µmol/L	5.98 mg/dL
Acetylsalicylic Acid	3.62 mmol/L	65.16 mg/dL
Ibuprofen	2.43 mmol/L	50.10 mg/dL
Acetaminophen	1324 µmol/L	20 mg/dL
Erythromycin	200 µmol/L	14.71 mg/dL
Gentamycin	65 µmol/L	3.11 mg/dL
Ampicillin	250 µmol/L	8.7 mg/dL
Prednisone	0.500 µmol/L	0.018 mg/dL
Methotrexate	3000 µmol/L	136 mg/dL
Etanercept	0.05 µmol/L	0.75 mg/dL
Simvastatin	5 µmol/L	0.21 mg/dL
Omeprazole	25 µmol/L	0.86 mg/dL
Rheumatoid Factor	Up to 400 IU/mL	

9.4 Exogenous interferences- Study of the coagulation effect on the CRP assay
Matrix comparison

Study materials :
Anticoagulant : heparin-lithium
Samples: individual donors from blood bank

Description:
38 samples were evaluated on Yumizen C1200 analyser using Yumizen C1200 CRP reagent.
For this study, each paired samples (sera and heparinized plasma) has been obtained from single donor.
Only native samples have been used for this study.

Sample (N)	Range (mg/L)	Slope (95%CI)	Intercept (95% CI)	R
38	5.09– 133.86	0.9398 (0.8973 – 1.007)	0.3413 (-0.1611 – +0.6459)	0.996

Conclusion :
The results show there is not significative difference between serum and plasma with heparin specimens
-> coagulation does not have an impact on CRP determination.

9.5 Method comparison with a comparator device

Study materials :
Samples: Anonymous remnants of human serum specimens collected from routine clinical laboratory.

Description:
This study has been carried out using recommendations found in the NCCLS (CLSI) EP-9A3 guidance.

These samples are in the candidate measuring range and comparator measuring range.

102 native samples have been assayed in duplicate, in ascendant order and descendant order on 6 working days.
Only the first replicate of each method will be used for the data analysis reported below.
The equation for the regression line using Passing Bablok was obtained.

Passing Bablok

Sample (N)	**Range (mg/L)**	**Slope (95%CI)**	**Intercept (95% CI)**	**R^2**
102	5. 25–144.48	0.9814 (0.9680 – 0.9976)	0.1305 (-0.1357 – +0.6287)	0.998

9.6 Reagent Stability

8.6.1. Closed stability

The closed stability was determined according to the CLSI guideline EP25-A.

Stability before opening:
Stable up to the expiry date on the label if stored at 2-10°C.

- **CRP**

The Shelf Life of Yumizen C1200 CRP is 24 months.

8.6.2 Open stability

The open stability was determined according to the CLSI guideline EP25-A.

On board reagent Stability:

The stability claim after opening, on-Board, is 8 weeks.

9.7 Reference range

The Reference Range was determined according to the CLSI guideline EP28-A3.

- **CRP**

Serum

- Adults data

80 “normal samples” from blood bank have been assayed with the method in evaluation. Each sample is assayed in duplicates.

The mean of the duplicate results for each subject was compared against reference ranges cited in literature. The verification studies support in the following reference ranges which were established through literature.

Adults:
20-60 years < 5 mg/L

Reference.:
Roberts WL, McMillin GA, Burtis CA, Bruns DE. Reference Information for the Clinical Laboratory, Tietz Textbook of Clinical Chemistry and Molecular Diagnostics; 4th Ed., Burtis CA, Ashwood ER, Bruns DE (Elsevier Saunders eds., St Louis, USA), (2006): 2263.

9.8 Proposed Labeling

The labeling is written as per the recommendations given in standard EN18113-2.
It takes into account the requirements of 21 CFR Part 809.10.

9.9 Conclusions for Performance Testing

The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that each device is substantially equivalent to its predicate device.