March 7, 2023

Visby Medical
Beth Lingenfelter
Vice President Regulatory and Clinical Affairs
3010 N 1st Street
San Jose, California 95134

Re: K220407
Trade/Device Name: Visby Medical Sexual Health Test
Regulation Number: 21 CFR 866.3393
Regulation Name: Device To Detect Nucleic Acids From Non-Viral Microorganism(S) Causing Sexually Transmitted Infections And Associated Resistance Marker(S)
Regulatory Class: Class II
Product Code: QEP, MKZ, LSL, OUY
Dated: February 10, 2022
Received: February 14, 2022

Dear Beth Lingenfelter:

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,

Himani Bisht -S

Himani Bisht, Ph.D.
Assistant Director
Viral Respiratory and HPV 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)*
K220407

Device Name
Visby Medical Sexual Health Test

Indications for Use *(Describe)*
The Visby Medical Sexual Health Test is a single-use (disposable), fully-integrated, automated Polymerase Chain Reaction (PCR) in vitro diagnostic test intended for use in point-of-care or clinical laboratory settings for the rapid detection and differentiation of DNA from Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis in self-collected female vaginal swab specimens using the Visby Medical Sexual Health Vaginal Specimen Collection Kit in a health care setting. The test results are to aid in the diagnosis of symptomatic or asymptomatic infections with Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis.

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

A. Submitter

Name:	Visby Medical, Inc.
Address:	3010 N. First Street San Jose, CA 95134
Phone:	1-833-468-4729
Contact:	Beth Lingenfelter
Date Prepared:	January 20, 2023

B. Device

Name of Device:	Visby Medical Sexual Health Test
Common Name:	Same
Classification Name:	Device to Detect Nucleic Acids from Non-Viral Microorganism(s) Causing Sexually Transmitted Infections and Associated Resistance Marker(s)
Regulatory Classification:	Class II
Regulation:	21 CFR 866.3393
Primary Product Code:	QEP
Additional Product Codes:	MKZ, LSL and OUY

C. Predicate Device

Visby Medical Sexual Health Click Test (K200748/CW200003)

D. Device Description

The Visby Medical Sexual Health Test (Visby Test) is a single-use (disposable), fully integrated, rapid, compact device containing a PCR-based assay for direct qualitative detection and differentiation of DNA from CT, NG, and TV. The test system includes the Visby Medical Sexual Health device, the Visby Medical power supply, the Visby Medical Vaginal Specimen Collection kit, and fixed-volume transfer pipettes. The device processes self-collected vaginal swab samples by automatically performing all steps required to complete lysis, polymerase chain reaction, and amplicon detection.

The patient uses the Visby Medical Vaginal Specimen Collection Kit to self-collect a vaginal specimen with the provided flocked swab, and then the patient elutes the specimen into the Visby Medical Collection Media. The test operator transfers the collection media containing the patient specimen into the sample port of the device using the provided fixed-volume pipette where it rehydrates a lyophilized internal process

control. The sample enters a lysis module, where the DNA of the sample and the internal process control are extracted using a combination of chemical lysis and high temperature. The extracted DNA enters a mixing chamber where it rehydrates lyophilized PCR reagents, followed by thermocycling to amplify target DNA. If present, the amplified pathogen target (CT, NG, and/or TV) and internal process control hybridize to specific probes located on a flow channel. Detection of the target-specific PCR product is accomplished via an enzyme-linked colorimetric assay using streptavidin bound horseradish peroxidase (HRP) and a colorimetric substrate that forms a purple precipitate. Test results can be expected in approximately 30 minutes: a green check mark will appear, and a purple color will appear in the “Results Valid” spot, indicating a valid test. A purple spot adjacent to “Chlamydia,” “Gonorrhea,” and/or “Trichomoniasis” signifies the presence of amplified CT, NG, and/or TV DNA in the sample.

Vaginal self-collection kits containing a tube of collection media compatible with the Sexual Health test and a collection swab are also packaged separately. External controls recommended in the product labeling are commercially available from a different manufacturer.

E. Intended Use

The Visby Medical Sexual Health Test is a single-use (disposable), fully integrated, automated Polymerase Chain Reaction (PCR) *in vitro* diagnostic test intended for use in point-of-care or clinical laboratory settings for the rapid detection and differentiation of DNA from *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* in self-collected female vaginal swab specimens using Visby Medical Sexual Health Vaginal Specimen Collection Kit in a health care setting. The test results are to aid in the diagnosis of symptomatic or asymptomatic infections with *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*.

F. Substantial Equivalence

The Visby Test is an updated version of the Visby Medical Sexual Health Click test (Click Test, the predicate). The Visby Test has no changes to the PCR primer and probe sequences, reagent formulations, detection method, or result interpretations.

Both devices have a similar design and are composed of the same materials. The Visby Test was developed to further simplify the user interface and to enable the automated manufacture process of the device.

The following table compares the Visby Test to the Click Test and outlines the similarities between the two tests.

Characteristics	Predicate Click Test	Subject Device Visby Test
Principle of Operation	An automated multiplex polymerase chain reaction with colorimetric detection.	Same
Analyte	DNA	Same
Organisms Detected	*Chlamydia trachomatis* (CT) *Neisseria gonorrhoeae* (NG) *Trichomonas vaginalis* (TV)	Same
Patient Population	Asymptomatic and symptomatic female patients	Same
Intended Use	The **Visby Medical Sexual Health Click Test** is a single-use (disposable), fully integrated, automated Polymerase Chain Reaction (PCR) in vitro diagnostic test intended for use in point-of-care or clinical laboratory settings for the rapid detection and differentiation of DNA from *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* in self-collected female vaginal swab specimens collected using Visby Medical Sexual Health Vaginal Specimen Collection Kit in a health care setting. The test results are to aid in the diagnosis of symptomatic or asymptomatic infections with *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*.	Same, only change is to the name of the device. The **Visby Medical Sexual Health Test** is a single-use (disposable), fully integrated, automated Polymerase Chain Reaction (PCR) in vitro diagnostic test intended for use in point-of-care or clinical laboratory settings for the rapid detection and differentiation of DNA from *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* in self-collected female vaginal swab specimens collected using Visby Medical Sexual Health Vaginal Specimen Collection Kit in a health care setting. The test results are to aid in the diagnosis of symptomatic or asymptomatic infections with *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis.*
Specimen Type	Patient-collected vaginal swab in Visby Collection Media	Same
CLIA Complexity Level	CLIA waived	Same
Quality Control	Internal electronic and process controls External Controls (by Zeptometrix)	Same

Characteristics	Predicate Click Test	Subject Device Visby Test
Reagents	Target specific primers Target specific capture probes Lyophilized PCR reagent Enzyme linked colorimetric reagents of visualization of target amplicon	Same
Results interpretation	Operator visually interprets test results	Same
Time to result	Approximately 30 minutes	Same

G. Summary of Performance Data

Comparison of Limit of Detection between the Visby Test and Click Test

This study provides objective evidence that the LoD for the Visby Test is comparable to that of the Click Test. Negative pooled clinical vaginal sample in Visby Collection Media was spiked at the LoD that was established with the Click Test and tested with 20 Visby devices and 20 Click devices. If at least 19/20 devices returned a positive test result, the organism was diluted 3-fold and the testing was repeated until the detection rate was <19/20 for both the Click and Visby test. The LoD values were determined to be equivalent if the lowest concentrations of organism with at least 19/20 detection rate from the two devices were within 3-fold of each other. The results in Table 1 confirm that the LoD between the Click Test and Visby Test are comparable.

Table 1. LoD comparison between Visby Test and the Click Test

Organism	LoD Multiple	Target Concentration	Hit Rate (Positive Valid Devices / Total Valid Devices Tested)	
			Click Test	Visby Test
CT Serovar H (VR-879)	1x	16.00 EB/mL	20/20	20/20
	1/3x	5.33 EB/mL	13/20	18/20
CT Serovar D (VR-885)	1x	5.90 EB/mL	20/20	20/20
	1/3x	1.97 EB/mL	11/20	19/20
	1/9x	0.66 EB/mL	7/20	10/20
NG	1x	6.20 cfu/mL	19/20	20/20
	1/3x	2.06 cfu/mL	10/20	19/20

(ATCC 49226)	1/9x	0.68 cfu/mL	5/20	9/20
NG (ATCC 19424)	3x	17.1 cfu/mL	20/20	20/20
	1x	5.7 cfu/mL	17/20	20/20
	1/3x	1.9 cfu/mL	17/20	19/20
	1/9x	0.63 cfu/mL	8/20	9/20
TV (ATCC 30001)	1x	1.20 troph/ mL	19/20	20/20
	1/3x	0.40 troph/mL	20/20	19/20
	1/9x	0.13 troph/mL	16/20	16/20
TV (ATCC 30238)	1x	0.24 troph/mL	20/20	20/20
	1/3x	0.08 troph/mL	17/20	17/20

Reproducibility

The reproducibility study of the Visby Test was conducted at three (3) CLIA waived study sites. The operators performing the testing were non-laboratorians representing healthcare professionals that may be encountered at such sites. The study evaluated seven (7) panel members that were prepared using cultured organisms in negative pooled clinical vaginal swab matrix (previously determined to be negative for CT, NG, TV). The study was performed with negative (unspiked), low positive (1X LoD), and moderate positive (3-5X LoD) samples.

A total of six (6) study operators (2 operators at each site) tested the panel three (3) times each testing day, over six (6) non-consecutive days. Three reagent lots were used in the study. A summary of the results (count correct / total count) and % agreement with expected results for each panel member by site and overall is presented in Table 2.

Table 2. Summary of Reproducibility Study Results for the Visby Test

Panel Member	Site 1	Site 2	Site 3	Overall Agreement	
	% Agreement (count)	% Agreement (count)	% Agreement (count)	% Agreement (count)	95% CI
CT Moderate Positive (64.0 EB/mL)	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%
CT Low Positive (16.0 EB/mL)	97.2% (35/36)	100.0% (36/36) [a]	100.0% (36/36)	99.1% (107/108)	94.9%-99.8%
NG Moderate Positive (24.8 cfu/mL)	100.0% (36/36)	100.0% (36/36)	97.2% (35/36)	99.1% (107/108)	94.9%-99.8%
NG Low Positive (6.2 cfu/mL)	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%
TV ModeratePositive (4.8 troph/mL)	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%
TV Low Positive (1.2 troph/mL)	97.2% (35/36)	97.2% (35/36) [b]	94.4% (34/36)	96.3% (104/108)	90.9%-98.6%
Negative	97.2% (35/36) [c]	100.0% (36/36)	97.2% (35/36) [c]	98.1% (106/108)	93.5%-99.5%

[a] One CT Low Positive sample was unexpectedly positive for TV
[b] One TV Low Positive sample was unexpected positive for CT
[c] One Negative sample was unexpectedly positive for TV

Clinical Comparison Study

Three studies were conducted to evaluate the equivalence of performance between the Visby Test and the Click Test.

Multicenter study with Untrained Operators

This study was conducted in CLIA Waived (CW) testing environments at three study sites using de-identified, frozen, self-collected vaginal swab specimens that are a subset of patient samples previously characterized in the clinical study for the Click Test.

A total of 30 CT positive (based on comparator results from the clinic study for Click Test, and this is the same for other analytes and negative sample), 20 NG positive, 30 TV positive and 33 negative vaginal swab specimens were selected for the study. Six (6) untrained study operators (two operators at each site) conducted the Visby testing.

The frozen samples were de-identified, randomized, and blinded so that the study staff and test operators did not know the expected results. Operators thawed the samples and tested them on-site using the Visby Test by following the instructions in the Quick Reference Guide (QRG). The results of the Visby Test were compared to the recorded result of the Click Test. Of the 102 samples included in the study, two samples had an initial invalid test result (2.41%, 95% CI: 0.66%-8.37%). One sample was excluded from the data analysis because it was invalid upon retesting. There were no additional

exclusions. Table 3 summarizes the concordance between the Click test results and the Visby test results.

Table 3. Clinical Performance of the Visby Test compared to the Click test performed by untrained operators

Target	N	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
CT	101	30	0	71	0	100.0% (88.6%-100.0%)	100% (94.9%-100.0%)
NG	101	20	0	81	0	100.0% (83.9%-100.0%)	100.0% (95.5%-100.0%)
TV	101	30	3	68	0	100.0% (88.6%-100.0%)	95.8% (88.3%-98.6%)

PPA=Positive Percent agreement; NPA=Negative Percent Agreement.
TP=true positive; FP=false positive; TN=true negative; FN=false negative.

Single Center Study with Trained Operators

A second clinical method comparison study was conducted at one site by trained operators using de-identified, frozen, archived self-collected vaginal swab specimens in Visby Medical Collection Media. The specimens tested in this study include all specimens with sufficient volume from the original clinical study of the Click Test as well as archived and banked frozen self-collected samples from two other previous Visby Medical studies. Testing was conducted by seven trained operators over seven days under variable lighting conditions throughout the day. The specimens were randomized and blinded so that the test operators did not know the expected results.

A total of 359 specimens were tested in this study. Operators thawed the samples and tested them with both the Visby Test and the Click Test if sufficient sample volume was present. Specimens without sufficient volume to run on both devices were tested only on the Visby Test, and the original Click Test results were used for the comparison.

Of the 359 specimens included in the study, one specimen did not have sufficient volume to run on any test and thus was excluded from the study. Of the remaining 358 specimens tested on the Visby Test, 11 (3.1%) had an initial invalid test result. As a final result, seven specimens were excluded from performance calculation due to insufficient sample volume for retest or failure to obtain a valid retest result. Therefore, a total of 351 specimens were included in the performance table.

Table 4 summarizes the concordance of the results between the Click Test and the Visby Test.

Table 4. Performance of Visby Test Compared to Click Test - Clinical Specimens

Visby Test vs. Click Test							
Target	**N**	**TP**	**FP**	**TN**	**FN**	**PPA**	**NPA**
CT	351	116	3	232	0	100.0% (95% CI: 96.8% - 100.0%)	98.7% (95% CI: 96.3% - 99.6%)
NG	351	34	0	317	0	100.0% (95% CI: 89.9% - 100.0%)	100.0% (95% CI: 98.8% - 100.0%)
TV	351	100	4	240	7[a]	93.5% (95% CI: 87.1% - 96.8%)	98.4% (95% CI: 95.9% - 99.4%)

a. TV PIS (based on the original clinical study for Click Test) for all seven specimens were negative.

Contrived specimens spiked at low organism concentrations

To further evaluate the performance of the Visby Test with samples containing low levels of the target organisms, samples were spiked at 1.5x LoD, 2x LoD and 3x LoD levels for each target in individual clinical matrices. Twenty (20) CT positive, 20 NG positive, 20 TV positive and 20 negative samples were tested on both the Visby Test and Click Test by four trained operators at a single site. Testing was performed over two days under various lighting conditions in a randomized and blinded fashion. All 80 contrived samples yielded valid results and are included in the final data analysis.

Table 5 summarizes the concordance of the results between the Visby Test and the Click Test when testing contrived samples.

Table 5. Performance of Visby Test Compared to Click Test - Contrived Samples

Organism	**Concentration**	**Correct Results / Total Tested**	
		Click Test	**Visby Test**
CT	1.5x LoD	6/6	5/6
	2x LoD	10/10	9/10
	3x LoD	4/4	4/4
NG	1.5x LoD	5/6	5/6
	2x LoD	9/10	10/10
	3x LoD	4/4	4/4
TV	1.5x LoD	6/6	6/6
	2x LoD	10/10	10/10
	3x LoD	4/4	4/4
Negative	N/A	20/20	19/20*

* One device was unexpectedly positive for TV