August 8, 2019

binx health, Inc.
Sarah Kalil
Regulatory Advisor
77 N. Washington Street, 5th Floor
Boston, Massachusetts 02114

Re: K191352
Trade/Device Name: binx health io CT/NG Assay
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, LSL, MKZ, NSU
Dated: May 20, 2019
Received: May 20, 2019

Dear Sarah Kalil:

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,

Steven Gitterman, M.D., Ph.D.
Deputy Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) SUMMARY

SUBMITTER NAME:	binx health, Inc.
SUBMITTER ADDRESS:	77 N. Washington Street 5th Floor Boston, MA 02114 USA
CONTACT PERSON:	Sarah Kalil Regulatory Advisor binx health, Inc. Phone: (646) 847 8573 Email: sarah.kalil@mybinxhealth.com
DATE PREPARED:	20th May 2019
DEVICE TRADE NAME:	Binx health *io* CT/NG Assay
CLASSIFICATION:	21 C.F.R. § 866.3393 (Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections) Class II
PRODUCT CODE:	QEP
SUBSEQUENT PRODUCT CODES:	LSL, MKZ, NSU
REVIEW PANEL	Microbiology
PREDICATE DEVICES:	BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay (K091730) and BD ProbeTec *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay (K091724) on the BD Viper™ System (Becton Dickinson, Sparks, MD).
INTENDED USE:	The binx health *io* CT/NG Assay, when tested using the binx health *io* Instrument, is a fully automated, rapid, qualitative test intended for use in point-of-care or clinical laboratory settings for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in female vaginal swab specimens collected either by a clinician or self-collected by a patient in a clinical setting, to aid in the diagnosis of symptomatic or asymptomatic infection in female patients with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.

DEVICE DESCRIPTION**:**

The binx health *io* CT/NG Assay System (the "binx *io* System", "binx *io* CT/NG Assay" or the "System") is a rapid qualitative *in vitro* diagnostic system consisting of the following:

1. The binx *io* Instrument for running the Cartridge (the "Instrument")
2. The binx *io* CT/NG Cartridge (the "CT/NG Cartridge", "Cartridge" or "Cartridges"), which contains all the necessary reagents to perform the binx *io* CT/NG Assay (the "Assay") on the binx *io* Instrument
3. A single-use, fixed-volume transfer pipet (packaged with the Cartridge) for transferring the sample to the Cartridge
4. A female Vaginal Swab Specimen Collection Kit consisting of a swab and a sample Collection tube containing preservation medium (the "Vaginal Swab Specimen Collection Kit")

The binx *io* CT/NG Cartridge is a single-use assay-specific cartridge for use on a single patient. All reagents are contained in the Cartridge as a combination of liquid reagents in blister packs and dried reagents. The Instrument is a small, bench top, fully integrated Instrument that uses air pressure to open and close valves on the CT/NG Cartridge which, in turn, controls the movement of solutions within the Cartridge; the Instrument takes full control of the Cartridges once they are inserted. The operation of the Instrument requires a minimal number of steps that a user follows via a graphical user interface (GUI) screen to load the Cartridge onto the Instrument. Once the Cartridge is loaded, no further interaction by the user is required as no sample preparation is needed. Turnaround time from adding a raw patient sample to a result on the Instrument takes about 30 minutes.

The Vaginal Swab Collection Kit consists of a sterile flocked swab and a tube of preservative medium. The Cartridge has a visual sample loading indicator window which turns from light to dark to confirm to the user that a sample has been added to the Cartridge.

The Cartridge has three fully automated assay steps, (i) sample preparation to isolate and purify target DNA, (ii) ultra-rapid polymerase chain reaction (PCR), which amplifies specific regions of DNA from the target organisms, and (iii) a proprietary electrochemical detection to identify the presence of amplified DNA.

When the specimen is added to the Cartridge, it is automatically mixed with a lysis solution to disrupt the cells present and release DNA which also rehydrates the Internal Process Control (IPC) sample. DNA extraction takes place and the eluted DNA is transferred to a homogenization chamber.

Ultra-rapid PCR is carried out using sequence-specific primers for CT, NG (two separate genomic targets) and the IPC.

Amplified target DNA is detected by hybridization to electrochemically labeled probes and cleavage of the label using a double-strand specific exonuclease. The free label diffuses to the electrode surface and generates an electrical current measured at a distinct voltage in nano Amps (nA) for each electrochemical label used.

The presence of a measurable peak to a fixed cut-off parameter for each target returns a qualitative result with no requirement for interpretation or calculations.

INTERNAL PROCESS CONTROL

The Assay also incorporates a positive IPC which is processed along with a patient sample and therefore is exposed to the same testing steps as the sample from DNA extraction and purification through to detection.

The IPC verifies all aspects of the Assay process have functioned as expected. In an Assay where CT and/or NG is not detected, the IPC is measured by the Instrument to ensure it is within an acceptable range to validate a negative result. If it is outside the acceptable range the Instrument will return an "Assay Invalid" message and no result will be displayed or recorded against that specimen. If it is within the acceptable range the result(s) "CT Not Detected" and/or "NG Not Detected" will be displayed and recorded by the Instrument.

ASSAY OUTCOMES

Qualitative results are provided to the user in text format only. Assay results are displayed with the Specimen ID and Assay type. To maintain patient confidentiality, the Patient ID (if one has been entered) will not be displayed on the same screen as the Assay result.

The results shown below are the only results the Instrument will return following completion of a test.

Assay Result	Interpretation of Assay Result
CT Not Detected	*Chlamydia trachomatis* target DNA **was not detected** in the patient specimen. The IPC passed specification. This is a valid result.
CT Detected	*Chlamydia trachomatis* target DNA **was detected** in the patient specimen. This is a valid result.
NG Not Detected	At least one of the DNA targets for *Neisseria gonorrhoeae* **was not detected** in the patient specimen. The IPC passed specification. This is a valid result.
NG Detected	Both DNA targets for *Neisseria gonorrhoeae* **were detected** in the patient specimen. This is a valid result.
Assay Invalid	The presence or absence of the DNA targets for *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* **could not be ascertained** in the patient specimen. If a CT or NG Not Detected result is obtained, and the IPC was outside the acceptable range indicating a failure in the Assay process. The Assay should be repeated using the same patient specimen.
User Aborted	A user cancelled the Assay. No result is given.
Error	An internal fault occurred that terminated the Assay before it finished.

PERFORMANCE EVALUATION:

ANALYTICAL PERFORMANCE

Analytical testing was performed to evaluate the performance of the binx *io* CT/NG Assay using the following studies:

Analytical sensitivity: Limit of Detection

Studies were carried out to determine the analytical limit of detection (LoD) of the binx *io* CT/NG Assay using cellular CT and NG material, for which the genome equivalents (GE)/mL were quantified. Two cartridge lots were used for each estimate of LoD to enable a lot to lot reproducibility comparison.

At least five separate input concentrations were used to cover a wide range (0.01-99%) of detection rates and each input concentration was tested with at least 20 replicates. A probit regression analysis was used to model the 'CT Detected/NG Detected' rate and identify the concentration level that demonstrated a detection rate of 95%. The LoD was then verified for each CT serovar and each NG strain, using a further total of 40 Cartridges per serovar/strain per Cartridge lot using two further preparations of the claimed LoD generated by two different operators. The LoD for each CT serovar and NG strain was set as the highest value generated from the two reagent lots and of the two tested serovars/strains.

LoD of CT serovars and NG strains

Organism	GE/mL	IFU/mL	CFU/mL
CT serovar E (ATCC-VR-348B)	407.4	5.6	N/A
CT serovar F (ATCC-VR-346)	755.5	0.3	N/A
NG strain ATCC 49226	245.6	N/A	2.1
NG strain ATCC 700825	206.1	N/A	2.5

Analytical reactivity (Inclusivity)

Analytical reactivity of additional CT serovars and NG strains was evaluated in the LoD studies described above.

CT serovars B, Ba, C, D, G, H, J, K, L2, nvCT were detected at 377.8 GE/mL. Serovars A, I, L1, L3 were detected at 755.5 GE/mL in at least 19/20 replicates.

Thirty additional NG strains (including two fluoroquinolone resistant isolates) and the reported detectable level was confirmed by testing replicates of three at or near the LoD of the 30 NG strains tested, 16 strains were detected at 245.6 GE/mL in all three replicates. The remaining 14 strains were further tested, and all were detected at 1,228.0 GE/mL in ≥19/20 replicates.

Analytical reactivity: Exclusivity

A panel of sixty-two species was investigated for cross-reactivity using cultured organisms at a concentration of 1×10^6 CFU/mL for bacteria, 1×10^5 PFU/mL for viruses or, GE, equivalent to a concentration of 2 ng/mL of genomic DNA generated by reverse transcription as available. Two further species were evaluated *in silico* by bioinformatic analysis of the genetic targets used in the Assay against the published genome sequences for these organisms. All isolates were reported as CT Not Detected/NG Not Detected with the exception of one strain of *Neisseria sicca* which gave a single CT Detected result from 20 replicates and may therefore be cross-reactive with the CT analyte.

Microorganisms tested in the binx *io* CT/NG Assay

*Bacteriodes fragilis**	*Neisseria meningitidis Serogroup D**
*Bacteriodes ureolyticus**	*Neisseria meningitidis Serogroup W135**
*Clostridium perfringens**	*Neisseria meningitidis Serogroup Y**
Corynebacterium genitalium	*Neisseria cinerea*
Corynebacterium xerosis	*Neisseria denitrificans*
Escherichia coli	*Neisseria elongata* (4)
*Gardnerella vaginalis**	*Neisseria gonorrhoeae**
*Haemophilus ducreyi**	*Neisseria flava*
Herpes simplex virus 1*	*Neisseria flavescens* (3)
*Homo sapiens**	*Neisseria lactamica* (3)
Human papilloma virus 16*	*Neisseria mucosa* (4)
Kingella dentrificans	*Neisseria perflava* (2)
Kingella kingae	*Neisseria polysaccharea*
Lactobacillus acidophilus	*Neisseria sicca* (4) *
Lactobacillus brevis	*Neisseria subflava* (2)
Lactobacillus jensenii	*Trichomonas vaginalis*
Lactobacillus lactis	*Ureaplasma urealyticum**
Moraxella lacunata	*Ureaplasma parvum**
Staphylococcus epidermidis	*Atopobium vaginae**
Streptococcus agalactiae	*Bifidobacterium longum**
Candida albicans	BVAB-2†
Candida glabrata	*Enterococcus faecalis*
Candida parapsilosis	Herpes Simplex Virus 2*
*Chlamydia pneumoniae**	*Klebsiella pneumoniae*
*Chlamydia psittaci**	*Megasphaera* type 1†
*Mycoplasma genitalium**	*Mobiluncus curtisii**
*Mycoplasma hominis**	*Mobiluncus mulieris**
*Neisseria meningitidis Serogroup A**	*Peptostreptococcus anaerobius**
*Neisseria meningitidis Serogroup B**	*Proteus mirabilis*
*Neisseria meningitidis Serogroup C**	*Pseudomonas aeruginosa*
-	*Staphylococcus aureus*
-	*Chlamydia trachomatis**

(n) number of strains tested

*Organisms tested with genomic DNA (2 ng/mL)

† *In silico* analysis

Analytical specificity: Interference

The analytical performance of the CT/NG Assay was evaluated in the presence of a panel of potentially interfering substances that may be found in vaginal swab specimens. The substances were diluted to the concentrations shown in the table below and spiked into negative vaginal matrix. The substances were tested in the absence of CT and NG (negative) and at 2 x LoD of both CT serovar F (ATCC VR-346) and NG strain ATCC 49226. No interference was observed.

Interfering substances tested in the binx *io* CT/NG Assay

Substance	**Concentration**
Human blood	10% (v/v)
Contraceptive Jelly	0.25% (v/v)
Mucus	0.8% (v/v)
Seminal fluid	5.0% (v/v)
Vaginal Moisturiser	0.25% (w/v)
Anti-fungal cream (Canesten)	0.25% (v/v)

Anti-fungal cream (Daktarin)	0.25% (v/v)
Vaginal lubricant	0.25% (v/v)
Feminine anti-itch cream (2% lidocaine)	0.25% (v/v)
Leukocytes	$1x10^6$ cells/mL
Progesterone	7 mg/mL
β-Estradiol (Estrace cream)	0.25% (v/v)
Anti-viral cream (Acyclovir)	0.25% (v/v)
Haemorrhoidal cream	0.25% (v/v)

Microbial Interference

The performance of the CT/NG Assay was evaluated when 2x LoD of both CT serovar F (ATCC VR-346) and NG strain ATCC 49226 were spiked into negative vaginal matrix, aliquots of which were subsequently spiked with a panel of ten microorganisms (see Table 10) at a concentration of 1 x 10^5 CFU/mL. No interference was observed and an expected result of **CT, NG Detected** was obtained in all cases.

Panel of organisms used for microbial interference testing with vaginal swab matrix

Organism
Corynebacterium xerosis
Escherichia coli
Lactobacillus acidophilus
Lactobacillus brevis
Lactobacillus jensenii
Lactobacillus lactis
Staphylococcus epidermidis
Streptococcus agalactiae
Candida albicans
Candida glabrata

Precision: Reproducibility

The reproducibility of the CT/NG Assay was evaluated at point-of-care settings at three U.S. locations using two non-laboratorians as operators at each site. CT and NG organisms were seeded into pooled vaginal swab matrix at concentrations representing low positive (1x LoD), moderate positive (3x LoD) and high positive (2.26 x 10^5 GE/mL CT or 1.18 x 10^6 GE/mL NG) samples. Negative (non-seeded) pooled vaginal swab matrix samples were also included. The resulting panel of 11 specimens was tested twice per day for seven consecutive days by two operators at three sites (11 specimens x 2 replicates x 7 days x 3 sites x 2 operators). CT/NG Assays were performed according to the Assay procedure. The rate of agreement with expected CT and NG results for each panel member is shown.

Summary of reproducibility results in vaginal swab matrix: percent agreement by study site

Panel No.	Sample	Analyte	Site 1 % agreement	Site 2 % agreement	Site 3 % agreement	% Total Agreement
1	**CT: neg**	CT	92.9% (26/28)	100.0% (28/28)	92.9% (26/28)	**95.2% (80/84)**
	NG: 1.18 x 10^6 GE/mL	NG	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**

2	**CT: neg**	CT	89.3% (25/28)	96.4% (27/28)	92.9% (26/28)	**92.9% (78/84)**
	NG: 3x LoD	NG	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
3	**CT: neg**	CT	100.0% (28/28)	100.0% (28/28)	92.9% (26/28)	**97.6% (82/84)**
	NG: 1x LoD	NG	100.0% (28/28)	100.0% (28/28)	96.4% (27/28)	**98.8% (83/84)**
4	**CT: 2.26 x 10^5 GE/mL**	CT	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
	NG: neg	NG	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
5	**CT: 3x LoD**	CT	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
	NG: neg	NG	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
6	**CT: 1x LoD**	CT	96.4% (27/28)	92.9% (26/28)	100.0% (28/28)	**96.4% (81/84)**
	NG: neg	NG	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
7	**CT: 2.26 x 10^5 GE/mL**	CT	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
	NG: 1.18 x 10^6 GE/mL	NG	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
8	**CT: 2.26 x 10^5 GE/mL**	CT	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
	NG: 1x LoD	NG	100.0% (28/28)	96.4% (27/28)	100.0% (28/28)	**98.8% (83/84)**
9	**CT: 1x LoD**	CT	100.0% (28/28)	96.4% (27/28)	96.4% (27/28)	**97.6% (82/84)**
	NG: 1.18 x 10^6 GE/mL	NG	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
10	**CT: 1x LoD**	CT	100.0% (28/28)	92.9% (26/28)	100.0% (28/28)	**97.6% (82/84)**
	NG: 1x LoD	NG	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**
11	**CT: neg**	CT	92.9% (26/28)	100.0% (28/28)	92.9% (26/28)	**95.2% (80/84)**
	NG: neg	NG	100.0% (28/28)	100.0% (28/28)	100.0% (28/28)	**100.0% (84/84)**

Sample storage and stability

Specimen stability studies were carried out to determine the length of time samples can be stored prior to testing on the binx CT/NG Assay. Pooled vaginal swab matrix was spiked with 3x LoD for CT Serovar F (ATCC-VR-346), and NG (strain ATCC 49226). Twenty replicates were run immediately and a further 20 of each were run after samples had been stored for 25 hours at 25°C or eight days at 2-8°C.

All positive samples correctly returned CT Detected/NG Detected results, all negative samples correctly returned CT Not Detected/NG Not Detected except one sample after storage of eight days at 2-8ºC that generated a false positive result. The positive agreement for CT and NG was 100% at both t=25 hours at 25°C and t=8 days at 2-8°C. The study indicates that vaginal

swab samples are stable for up to 24 hours at 25°C and 7 days at 2-8°C prior to testing with the Assay.

Operational environment

A study was carried out to verify the performance of Instruments and Cartridges when run beyond the extremes of typical ambient temperatures and at high and low levels of relative humidity. Performance of the binx *io* Instruments was evaluated by placing the Instruments in validated and monitored environmental chambers held at a range of temperatures and humidity levels that were outside the typical normal Instrument operating range.

Summary of operational environment testing

Environmental Temperature (°C)	Environment Humidity (RH%)	Expected results: Positive samples	% correct results	Expected results: Negative samples	% correct results
9°C	40%	CT Detected NG Detected	100%	CT Not Detected NG Not Detected	100%
37°C	40%	CT Detected NG Detected	100%	CT Not Detected NG Not Detected	100%
22°C	83%	CT Detected NG Detected	100%	CT Not Detected NG Not Detected	100%
30°C	83%	CT Detected NG Detected	100%	CT Not Detected NG Not Detected	100%
20°C	15%	CT Detected NG Detected	100%	CT Not Detected NG Not Detected	100%

Open pack stability

A study was carried out to verify the performance of the Instrument and Cartridge when subjected to a range of temperature and humidity levels.

The study was carried out using CT/NG Cartridges tested with 4x LoD for CT serovar F (ATCC-VR-346) and NG strain ATCC 49226 spiked into eNAT buffer. Cartridges were removed from their packaging and samples (positives) or eNAT buffer (negatives) were added. Cartridges were placed in a controlled and monitored incubator for 1, 2, 3, 4, 5 and 6 hours at +30°C. In addition, a set of Cartridges were loaded with a sample and incubated for six hours at +30°C at low (≤20% Relative Humidity (RH)) and high humidity (≥60% RH) using a monitored environmental chamber.

All samples generated the expected results and verified that the CT/NG Assay generates the correct results when a sample is loaded into a Cartridge and stored at 30°C in both high and low humidity conditions following up to six hours storage.

Cartridge performance when run immediately from 2-8ºC storage

A study was carried out using Cartridges that had been stored at 2-8°C for a minimum of 12 hours using samples that had either been stored at room temperature or stored refrigerated at 2-8°C for a minimum of 12 hours. All replicates generated correct results.

Shipping stability

The performance of the Assay was assessed following simulated shipping conditions in order to demonstrate performance after undergoing two temporary storage and shipping cycles. This study was carried out using eNAT samples spiked with 4x LoD for positives, or eNAT buffer for negatives. All samples tested generated correct results.

ISTA3A testing

An ISTA (International Safe Transit Association) 3A study was carried out by an accredited test site followed by subsequent inspection and test performance. The study used a total of 50 Cartridges within a shipper of five cartons containing ten CT/NG Cartridges each. No damage was observed to the packaging or Cartridges and all Cartridges tested with 4x LoD

CT/NG spiked into eNAT buffer for positives and eNAT buffer for negatives generated correct results.

Cross contamination

A study was conducted to demonstrate that the CT/NG Cartridge prevents run-to-run cross contamination when negative samples containing pooled vaginal matrix were run following very high CT/NG double positive samples (containing 2.26×10^6 GE/mL CT and 1.18×10^7 GE/mL NG). The study consisted of four separate Instruments, with 50 Cartridges run per Instrument, alternating between negative samples and very high CT/NG double positive samples (200 Cartridges run across all instruments, comprising 100 negative and 100 very high positive). All negative samples were correctly detected as CT, NG Not Detected and all positive samples were correctly identified as CT, NG Detected.

Internal Control Function

A study was carried out to demonstrate the IPC function. The objective was to demonstrate that a Cartridge lacking internal control DNA would report an Assay Invalid result. A panel of conditions was tested including Cartridge manufactured specifically with no IPC present. All samples tested generated the expected results including the Cartridges with no IPC which delivered the expected Assay Invalid result.

All experiments carried out to evaluate analytical performance met established acceptance criteria.

CLINICAL PERFORMANCE

A prospective, multi-center study was carried out to evaluate the performance of the binx *io* CT/NG Assay with specimens collected at nine investigational sites throughout the U.S. The Assay was compared to the (i) Hologic Aptima Combo 2 (AC2) Chlamydia/Gonorrhea Assay run on Panther, (ii) BD ProbeTec *Chlamydia trachomatis* (CT) Q^x, and BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x assays run on the Viper XTR™, and (iii) Roche cobas CT/NG v2.0 test run on the cobas 4800 System. The three reference tests were used to form a Composite Infected Status (CIS) where a patient was considered infected if at least two out of the three reference tests were positive and not infected if at least two out of the three reference tests was negative. Vaginal swabs were obtained from women with and without symptoms of infection from a variety of clinical venues and both self-collected and clinician-collected vaginal swabs were tested.

Site personnel that carried out testing using the CT/NG Assay were, in the vast majority (96% overall), point-of-care personnel trained in the use of the binx *io* CT/NG System, but not trained or experienced in general laboratory testing procedures.

A total of 1,634 participants were enrolled into the Study. Twenty-one participants were ineligible or withdrew consent. Eighty-nine participants were excluded due to deviations to the study protocol. Of the 1,524 specimens for which a CIS could be determined, one specimen generated an Invalid result after three successive tests and was considered Indeterminate (IND) with respect to the Assay. This sample was excluded from the final data analysis.

A total of 1,523 vaginal swab specimens were fully evaluable. Of these, 736 were self-collected vaginal swabs (SCVS) and 787 were clinician-collected vaginal swabs (CCVS). Of the total number of vaginal specimens collected, 706 were from asymptomatic participants and 817 from symptomatic participants.

A total of 129 eligible subjects were classified as infected for CT, of which 62 were symptomatic and 67 were asymptomatic. A total of 1,394 participants were classified as not infected for CT, of which 755 were symptomatic and 639 were asymptomatic.

A total of 45 participants were classified as infected for NG, of which 29 were symptomatic and 16 were asymptomatic. A total of 1,478 participants were classified as not infected for NG, of which 788 were symptomatic and 690 were asymptomatic.

The median age of participants was 27, ranging from 16 to 74 years.

Composite Infected Status for *Chlamydia trachomatis* by symptom status

CIS	Comparator System			binx	Symptom		Total
	NAAT1	NAAT2	NAAT3	*io*	Sx	Asx	
NI	-	-	-	-	731	620	1351
NI	-	-	+	-	2	3	5
NI	-	+	-	-	5	7	12
NI	+	-	-	-	0	0	0
NI	-	-	IND	-	2	1	3
NI	-	IND	-	-	1	2	3
NI	IND	-	-	-	6	1	7
NI	-	-	-	+	8	5	13
NI	-	-	+	+	0	0	0
NI	-	+	-	+	0	0	0
NI	+	-	-	+	0	0	0
NI	-	-	IND	+	0	0	0
NI	-	IND	-	+	0	0	0
NI	IND	-	-	+	0	0	0
Total not Infected					755	639	1394
I	+	+	+	+	56	63	119
I	+	+	-	+	0	1	1
I	+	-	+	+	0	1	1
I	-	+	+	+	1	0	1
I	+	+	IND	+	0	0	0
I	+	IND	+	+	1	0	1
I	IND	+	+	+	1	0	1
I	+	+	+	-	1	2	3
I	+	+	-	-	2	0	2
I	+	-	+	-	0	0	0
I	-	+	+	-	0	0	0
I	+	+	IND	-	0	0	0
I	+	IND	+	-	0	0	0
I	IND	+	+	-	0	0	0
Total Infected					62	67	129

CIS = Comparator Infected Status NI = Not Infected I = Infected IND = Indeterminate
Sx = Symptomatic Asx = Asymptomatic

Composite Infected Status for *Neisseria gonorrhoeae* by symptom status

CIS	Comparator System			binx	Symptom		Total
	NAAT1	NAAT2	NAAT3	*io*	Sx	Asx	
NI	-	-	-	-	776	681	1457
NI	-	-	+	-	3	4	7
NI	-	+	-	-	0	0	0
NI	+	-	-	-	0	0	0
NI	-	-	IND	-	2	1	3
NI	-	IND	-	-	0	2	2
NI	IND	-	-	-	6	1	7
NI	-	-	-	+	0	0	0
NI	-	-	+	+	0	0	0
NI	-	+	-	+	0	0	0
NI	+	-	-	+	1	0	1
NI	-	-	IND	+	0	0	0
NI	-	IND	-	+	0	1	1
NI	IND	-	-	+	0	0	0
Total not Infected					788	690	1478
I	+	+	+	+	24	15	39
I	+	+	-	+	1	0	1
I	+	-	+	+	2	1	3
I	-	+	+	+	1	0	1
I	+	+	IND	+	0	0	0
I	+	IND	+	+	0	0	0
I	IND	+	+	+	1	0	1
I	+	+	+	-	0	0	0

I	+	+	-	-	0	0	0
I	+	-	+	-	0	0	0
I	-	+	+	-	0	0	0
I	+	+	IND	-	0	0	0
I	+	IND	+	-	0	0	0
I	IND	+	+	-	0	0	0
Total Infected					29	16	45

CIS = Comparator Infected Status NI = Not Infected I = Infected IND = Indeterminate
Sx = Symptomatic Asx = Asymptomatic

Results from the CT/NG Assay were compared to the CIS for CT for the determination of sensitivity, specificity and predictive values. Sensitivity and specificity for CT and NG by specimen type, symptom status and prevalence rates.

Clinical Performance of the binx health *io* CT/NG Assay against CIS for *Chlamydia trachomatis* with vaginal swab specimens

	N	TP	FN	TN	FP	Prevalence	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Asymptomatic	706	65	2	634	5	9.5%	97.0% (89.8% - 99.2%)	99.2% (98.2% - 99.7%)	92.9% (84.1% - 97.6%)	99.7% (98.9% - 100.0%)
Symptomatic	817	59	3	747	8	7.6%	95.2% (86.7% - 98.3%)	98.9% (97.9% - 99.5%)	88.1% (77.8% - 94.7%)	99.6% (98.8% - 99.9%)
Total	1523	124	5	1381	13	8.5%	96.1% (91.2% - 98.3%)	99.1% (98.4% - 99.5%)	90.5% (84.3% - 94.9%)	99.6% (99.2% - 99.9%)

N= Number of specimens TP = True Positive FN = False Negative TN = True Negative FP = False Positive
PPV = Positive Predictive Value NPV = Negative Predictive Value
Confidence Intervals (CI) for Sensitivity and specificity: Wilson Score Method
Confidence Intervals (CI) for NPV, PPV :Exact Method

Clinical Performance of the binx health *io* CT/NG Assay against CIS for *Neisseria gonorrhoeae* with vaginal swab specimens

	N	TP	FN	TN	FP	Prevalence	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Asymptomatic	706	16	0	689	1	2.3%	100.0% (80.6% - 100.0%)	99.9% (99.2% - 100.0%)	94.1% (71.3% - 99.9%)	100.0% (99.5% - 100.0%)
Symptomatic	817	29	0	787	1	3.5%	100.0% (88.3% - 100.0%)	99.9% (99.3% - 100.0%)	96.7% (82.8% - 99.9%)	100.0% (99.5% - 100.0%)
Total	1523	45	0	1476	2	3.0%	100.0% (92.1% - 100.0%)	99.9% (99.5% - 100.0%)	95.7% (85.5% - 99.5%)	100.0% (99.8% - 100.0%)

N= Number of specimens TP = True Positive FN = False Negative TN = True Negative FP = False Positive
PPV = Positive Predictive Value NPV = Negative Predictive Value
Confidence Intervals (CI) for Sensitivity and specificity: Wilson Score Method
Confidence Intervals (CI) for NPV, PPV :Exact Method

Overall clinical performance

Organism	No. of binx Pos/TP	Overall Sensitivity (95% CI)	No. of binx Neg/TN	Overall Specificity (95% CI)
CT	124/129	96.1% (91.2% - 98.3%)	1381/1394	99.1% (98.4% - 99.5%)
NG	45/45	100.0% (92.1% - 100.0%)	1476/1478	99.9% (99.5% - 100.0%)

Rate of Invalid Results

In cases where the Assay returned a Test Invalid result, the patient specimen was retested. The result of the retest was used in the analysis. A Test Invalid result was reported in 17 of the 1,541 cartridges tested (1.10%) in this study. If three successive assays returned a Test Invalid result on a single specimen this was recorded as Indeterminate. Of the 1,524 specimens for which a CIS could be determined, one specimen generated a final invalid (Indeterminate (IND)) result and was excluded from analysis.

Positive and Negative Predictive Values
The sensitivity and specificity of the binx health *io* CT/NG Assay when used with vaginal swabs, was used to calculate the hypothetical Positive Predictive Values (PPV) and Negative Predictive Values (NPV) at a range of hypothetical prevalence rates.

Hypothetical PPV and NPV: Female Vaginal Swab specimens

	***Chlamydia trachomatis* (CT)**				***Neisseria gonorrhoeae* (NG)**			
Prevalence %	**Sensitivity %**	**Specificity %**	**PPV %**	**NPV %**	**Sensitivity %**	**Specificity %**	**PPV %**	**NPV %**
1	96.1%	99.1%	51.9%	100.0%	100.0%	99.9%	91.0%	100.0%
5	96.1%	99.1%	84.9%	99.8%	100.0%	99.9%	98.1%	100.0%
10	96.1%	99.1%	92.2%	99.6%	100.0%	99.9%	99.1%	100.0%
15	96.1%	99.1%	95.0%	99.3%	100.0%	99.9%	99.4%	100.0%
20	96.1%	99.1%	96.4%	99.0%	100.0%	99.9%	99.6%	100.0%
25	96.1%	99.1%	97.3%	98.7%	100.0%	99.9%	99.7%	100.0%

SUBSTANTIAL EQUIVALENCE:

Item	**510(k) Device: binx *io* Assay binx *io* CT/NG System**	**Predicate Devices BD ProbeTec Q^x CT (K091724); and BD ProbeTec Q^x GC (K091730)**
Regulation	866.3393	K091724: 866.3120 K091730: 866.3390
Regulation Specialty	Microbiology	Microbiology
Device Class	Class II	K091724: Class I K091730: Class II
Technology	Automated multiplex polymerase chain reaction with electrochemical detection	Automated multiplex strand displacement amplification with fluorescence detection
Intended Use	The binx health *io* CT/NG Assay, when tested using the binx health *io* Instrument, is a fully automated, rapid, qualitative test intended for use in point-of-care or clinical laboratory settings for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in female vaginal swab specimens collected either by a clinician or self-collected by a patient in a clinical setting, to aid in the diagnosis of symptomatic or asymptomatic infection in female patients with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.	The BD ProbeTec *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay, when tested with the BD Viper System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Chlamydia trachomatis* DNA in clinician-collected female endocervical and male urethral swab specimens, patient–collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and Neat). The Assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid using an aliquot that is removed prior to processing for the BD SurePath Pap test. The Assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease. The BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay, when tested with the BD Viper System in Extracted Mode, uses Strand Displacement Amplification technology

		for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient–collected vaginal swab specimens (in a clinical setting), and male 2 and female urine specimens (both UPT and Neat). The Assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid using an aliquot that is removed prior to processing for the BD SurePath™ Pap test. The Assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.
Indications	Symptomatic and asymptomatic female patients	Same
Assay Target	DNA from *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*	Same
Specimen Types	Clinician-collected female vaginal swabs Patient-collected female vaginal swabs (in a clinical setting)	Clinician-collected female endocervical swabs Male urethral swabs Patient–collected vaginal swab specimens (in a clinical setting) Male & female urine (both UPT and Neat). Specimens collected in BD SurePath™
CT Analyte Target	CT Genomic DNA	CT cryptic plasmid DNA
NG Analyte Target	NG Genomic DNA	Same
Collection Kit	Vaginal Swab Collection Kit	Same
Nucleic Acid Extraction	Yes	Same
Assay Results	Qualitative	Same
Assay Controls	Internal Process Control External controls available but not supplied	Positive & negative run controls Automated control rehydration Extraction control Specimen processing control procedure
Instrument System	binx health *io*®	BD Viper™

Based on the data presented in this 510(k) Premarket Notification, the binx *io* CT/NG Assay has been shown to be substantially equivalent to the predicate device for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in female vaginal swab specimens.