April 2, 2026

Becton, Dickinson and Company
Joseph Basore
Sr. Staff Regulatory Affairs Specialist
7 Loveton Circle
Sparks, Maryland 21152

Re: K260184
Trade/Device Name: Onclarity Self-Collection Kit
Regulation Number: 21 CFR 866.2920
Regulation Name: Device for home collection and transportation of clinical specimens by lay users for infectious disease testing
Regulatory Class: Class II
Product Code: SEP
Dated: January 21, 2026
Received: January 21, 2026

Dear Joseph Basore:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production and process controls (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

HIMANI BISHT -S

Himani Bisht
Branch Chief
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)*
K260184

Device Name
Onclarity™ Self-Collection Kit

Indications for Use *(Describe)*
The Onclarity™ Self-Collection Kit is intended for the self-collection and transport of vaginal specimens for use with an FDA approved HPV molecular assay with which the collection device has been validated. The Onclarity™ Self-Collection Kit contains all of the necessary components for the self-collection of a vaginal specimen in a home or private setting. Specimen can be collected and shipped dry.

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

Onclarity™ Self-Collection Kit

K260184

Summary Preparation Date:

1/21/2025

Submitted by:

BD Integrated Diagnostic Solutions
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact:

Joseph Basore, Ph.D., RAC
Senior Staff Regulatory Affairs Specialist
Becton Dickinson and Company
7 Loveton Circle, Sparks, MD 21152 USA
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Proprietary Names:

Onclarity™ Self-Collection Kit

Common Names:

HPV at Home Self-Collection Kit

Regulatory Information

Regulation section: 21 CFR 866.2920 – Device for home collection and transportation of clinical specimens by lay users for infectious disease testing

Classification: Class II (Special Controls)

Panel: Microbiology (83)

Product Code(s): SEP

Predicate Device

Teal Wand (DEN240045)

Device Establishment

Registration Number: 1119779

Intended Use

The Onclarity™ Self-Collection Kit is intended for the self-collection and transport of vaginal specimens for use with an FDA-approved HPV molecular assay with which the collection device has been validated. The Onclarity™ Self-Collection Kit contains all of the necessary components for the self-collection of a vaginal specimen in a home or private setting. Specimens can be collected and shipped dry.

Special Conditions for Use Statement: For Prescription Use Only

Performance of this device has only been validated with the BD Onclarity HPV Assay (P160037/S017 and P160037/S024).

Special Instrument Requirements: None

Device Description

The Onclarity Self-Collection Kit is a prescription device that is used to collect and transport self-collected vaginal specimens from female patients in unsupervised home or similar private environments. Kits will be shipped to the patient when a valid prescription is obtained. Each kit can be used for collection of one vaginal specimen. The collected specimen is intended for testing with the BD Onclarity HPV assay on the BD Viper LT System or BD COR System and has two configurations to support the available collection and testing workflows ("Manual Workflow" and "Automated Workflow").

Test Principle

The Onclarity Self-Collection Kit includes a flocked swab consisting of a molded plastic applicator stick (comprised of a copolyester shaft). The tip of the applicator is coated with short nylon fibers arranged in a perpendicular fashion (Figure 1). Utilization of the this flocked swab entails the patient inserting the swab into the vaginal canal up to the colored demarcation line (also referred to as score mark) on the swab. The user subsequently turns the swab clockwise or counterclockwise for 10-30 seconds to collect the specimen, then removes the swab from the vaginal canal. For patients using the Onclarity™ Self-Collection Kit - Viper™ LT (Manual Workflow), the user then places the swab back into the plastic sheath packaging and mails to a designated laboratory for testing (Figure 2). For patients using the Onclarity™ Self-Collection Kit - COR™ (Automated Workflow), the user places the swab into the Onclarity™ Self-Collection Tube and breaks the swab at the red breakpoint shown in Figure 1 and then places the cap on the tube and mails to a designated laboratory for testing (Figure 3).

Figure 1. Swab for Automated Workflow

Figure 2. Swab for Manual Workflow

Figure 3. BD Onclarity HPV Self-Collection Tube for Automated Workflow

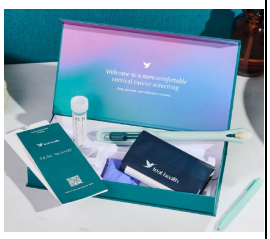
Substantial Equivalence[1]

Table 1 provides the similarities and differences between the submitted device and the legally marketed predicate device.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Table 1: Comparison to Predicate Device

Item	Predicate: Teal Wand (DEN240045)	Onclarity™ Self-Collection Kit	
Intended Use/Indications for Use Statement	The Teal Wand is a device for the self-collection of vaginal specimens for the purpose of collecting and transporting specimens for use in an FDA approved HPV molecular assay with which the collection device has been validated. The Teal Wand can be used at-home or in any private setting. Specimens can be collected, stored, and shipped dry in an empty vial.	The Onclarity™ Self-Collection Kit is intended for the self-collection and transport of vaginal specimens for use with an FDA approved HPV molecular assay with which the collection device has been validated. The Onclarity™ Self-Collection Kit contains all of the necessary components for the self-collection of a vaginal specimen in a home or private setting. Specimens can be collected and shipped dry.	
Regulation	21 CFR 866.2920	Same	
Product Code	SEP	Same	
Collection Type	Vaginal	Same	
Collection Setting	At Home or Private	Same	
Prescription Required	Yes	Same	
Kit Content	• Instructions Booklet (2), in English (1) and Spanish (1) • Product Information with Warnings, Precautions, and FAQs (1) • Teal Wand (1) • Empty Vial (with a label attached) (1) • Gloves (2) • Pen (1) • Rigid Safety Bag (1) • Return Mailer (with a US Postal Service mailing label attached) (1)	**Onclarity™ Self-Collection Kit - Viper™ LT (Manual Workflow)** • A reclosable box (UN 3373 Compliant Shipper to be used for transport of collected specimen to laboratory) containing: ▫ 1 Swab (packaged in plastic sheath. Sheath serves as the container for collected swab) ▫ 1 Instructions for Use (for self-collection) ▫ 1 Biohazard bag (with a label attached for recording collection date and patient information)	**Onclarity™ Self-Collection Kit - COR™ (Automated Workflow)** • A reclosable box (UN 3373 Compliant Shipper to be used for transport of collected specimen to laboratory) containing: ▫ 1 Swab (packaged in a peel pouch) ▫ 1 empty BD Onclarity HPV Self Collection Tube ▫ 1 Instructions for Use (for self-collection)

Item	Predicate: Teal Wand (DEN240045)	Onclarity™ Self-Collection Kit	
		• Return shipping instructions (provided by laboratory)	▫ 1 Biohazard bag (with a label attached for recording collection date and patient information) • Return shipping instructions (provided by laboratory)
Kit Image			
Collection Device Image			
Swab Rotations for Sample Collection	10 Rotations	Rotate for 10-30 seconds	
Specimen Return (by lay user) Timeframe	24 hrs	Same	
Sample Storage Conditions	59 F to 86 F	Ambient	
Shipment Type	Dry	Same	
Shelf-Life	12 months	36 months	

Analytical Performance

Specimen Shipping Stability

A specimen shipping stability study was conducted for a duration of 37.8 days to evaluate the stability of dry swab specimens for an anticipated 30-day dry storage period. The tested 37.8-day period included 10.1 days' exposure to conditions representing extreme cold and hot temperatures from collection to the point of receipt at the laboratory, and 27.7 days' dry storage at the laboratory after receipt. Additionally, following the above dry storage, samples were subjected to storage at different in-process steps (please refer to the last three rows under "Specimen Configuration" in the table below for these steps) to simulate possible wait time during testing. Positive swab samples were prepared by co-spiking SiHa (HPV 16) and Hela (HPV 18) cells at low positive

concentrations in the negative clinical vaginal matrix and then spiked directly onto swabs. Negative swab samples were prepared by spiking the negative clinical matrix directly onto swabs. Replicates of positive and negative samples were tested at baseline as well as at various storage stages. Specimens may be stored within the temperatures and timeframes defined below (Table 2).

Table 2: Transport and Storage Conditions for Self-Collected Vaginal Specimen in Plastic Sheath or BD Onclarity™ HPV Self Collection Tube

Specimen Configuration	Temperature	Time
Dry swab in plastic sheath or empty BD Onclarity™ HPV Self Collection Tube, *in transit* [a]	Ambient	7 days
Dry swab in plastic sheath or empty BD Onclarity™ HPV Self Collection Tube[a]	2-30 °C	30 days
	-20°C	30 days
In BD Onclarity™ HPV Self-Collection Tube or BD Onclarity™ HPV Self Collection Tube filled with diluent (after specimen transfer and prior to pre-warm)	Ambient	3 days
In BD Onclarity™ HPV Self-Collection Tube or BD Onclarity™ HPV Self Collection Tube filled with diluent, capped post pre-warm (after specimen transfer and sample pre-warm)	2-30 °C	3 days
	-20°C	3 days
In BD Onclarity™ HPV Self-Collection Tube or BD Onclarity™ HPV Self Collection Tube filled with diluent, punctured cap post pre-warm (after specimen transfer and sample pre-warm with punctured cap) [b]	2-30°C	3 days

[a] The date of specimen collection on the biohazard bag should be checked upon receipt. Specimens must be received by the laboratory within 7 days of the specimen collection date. Specimens received greater than 7 days from the specimen collection date should be rejected, and a new specimen should be requested. Specimens may be received at any time of day within the 7 days. Specimens received within the aforementioned transit duration may be tested up to 30 days from the date of collection.

[b] Punctured caps do not need to be replaced prior to retesting.

Onclarity Self-Collection Kit Swab Sterility and Shelf-life Stability

The flocked swab contained in the Onclarity Self-Collection Kit is sterilized using Ethylene Oxide (EO). Sterility Assurance Level and EO residues level of the tested devices meet required specifications. Real time aging and shelf-life stability tests, including visual inspection, seal strength, dye penetration, microbial barrier, and sterility, were performed and support a shelf-life stability of 36 months.

Linearity

Not applicable.

Limit of Detection at the Clinical Cutoff (hereafter referred to as LoD)

The LoD at the clinical cutoff for vaginal specimen are presented in the table below. HPV positive samples were prepared by using SiHa (HPV16), HeLa (HPV18), and MS751 (HPV45) cell lines and plasmids for the remaining 11 genotypes. Studies were performed on both BD Viper LT and BD COR Systems and results are the same between the two systems.

Target	LOD (Cells or Copies/mL)[a]	95% Confidence Interval	
		Lower	Upper
SiHa (HPV16)	9.7	7.7	13.4
HeLa (HPV18)	51	46	56
MS751 (HPV45)	305	284	343
HPV31	692	650	817
HPV33	1,376	1,272	1,451
HPV35	1,552	1,317	1,780
HPV39	1,531	1,419	1,685
HPV51	1,229	1,155	1,353
HPV52	833	744	934
HPV56	836	737	911
HPV58	2,990	2,656	7,818
HPV59	772	722	899
HPV66	701	646	767
HPV68	2,079	1,995	2,125

a. Concentrations are provided in cells/mL (for HPV 16, 18, and 45) or copies/mL (for 11 other HR HPV genotypes) in the 3.0 mL sample input tube for BD Onclarity HPV Self Collection Diluent.

Interfering Substances

A study was performed to evaluate whether substances commonly used by lay users in home settings may interfere with the detection of HPV using Onclarity Self-Collection Kit collected samples. Both positive and negative contrived samples were tested with and without the potential interfering substances. The positive samples were prepared by co-spiking SiHa (HPV16), HeLa (HPV18), and MS751 (HPV45) cell lines at 3xLoD. A subset of interfering substances study data was leveraged from P160037-S017. Substances tested are described in the following table. The indicated concentrations represent the tested concentration of a substance, when assessed with the BD Onclarity HPV Assay, that did not result in interference.

Potential Interfering Substance	Concentration without Interference
KY Jelly Personal Lubricant	8% (w/v) [a]
VCF Vaginal Contraceptive Film	3% (w/v)
Nonoxynol-9 Contraceptive Gel, 4%	1% (w/v) [a]
Monistat 3	1.8% (w/v)
Clotrimazole 7	10% (w/v)
Tioconazole Ointment, 6.5%	1% (w/v)
Clindamycin Vaginal Cream	9% (w/v)
Summer's Eve Douche	10% (v/v)
Zovirax (Acyclovir) Cream	10% (w/v)
Vandazole Gel (Metronidazole Vaginal Gel, 0.75%)	10% (w/v)
Summer's Eve Deodorant	1% (w/v) [a]
Replens Moisturizer	2.8% (w/v) [a]
Bovine Mucin	7.8% (w/v) [a]
Progesterone	20 ng/mL
Estradiol	1.2 ng/mL
Whole Blood	1% (v/v) [a]
Leukocytes	$1x10^6$ cells/mL
Semen	10% (v/v)
Estrace, 0.01%	7% (w/v) [a]

Crinone, 4%	2% (w/v) [a]
Preparation H	6% (w/v) [a]
Hand Soap (Softsoap)	0.1% (w/v) [a]
Hand Sanitizer (Purell)	7.1% (w/v)
Lotion (Gold Bond)	1% (w/v) [a]
Sunscreen (Wegmans Sport)	1% (w/v) [a]
Water	5% (w/v)

[a] May interfere with the detection of HPV when present at higher concentration than what is indicated in the table.

Assay Cutoff

Not applicable.

Traceability

Not applicable.

Usability and Comprehension study

Device usability and user comprehension of the Onclarity Self-Collection Kit-COR was assessed in female participants aged 25 to 64 years old in a simulated home environment to evaluate user's ability to self-collect a vaginal sample and prepare the vaginal sample for mailing according to the provided instructions. The study involved 60 participants representing a range of education levels. Usability and comprehension study results demonstrated high user comprehension and ability to execute procedural steps across the study participants. A second usability study was conducted in 58 female participants aged at 25 or above to evaluate the users' ability to follow the collection instructions to self-collect vaginal swab at home. All participants demonstrated success in completing the at home collection tasks. Vaginal self-collection procedure has been demonstrated to be easy to perform and safe for the users.

Clinical Performance

Study #1

A prospective clinical study (LMI-001-A-S01) was conducted to provide data supporting the performance of the Onclarity Self-Collection Kit for use with the BD Onclarity HPV Assay. Vaginal swabs were self-collected in a simulated home environment in a U.S. population. This study was conducted under the NCI-sponsored Cervical Cancer "Last Mile" Initiative "Self-collection for HPV testing to Improve Cervical Cancer Prevention" (SHIP) trial. A total of 554 subjects, from 13 colposcopy clinics across the continental United States and Puerto Rico, were enrolled in the study from September 2024 through February 2025. The study enrolled women referred for colposcopy or direct cervical excisional procedures (without intermediate colposcopy) based on abnormal cervical cancer screening conducted within 12 months preceding the referral visit. Women who were attending clinic for excisional procedures due to prior abnormal biopsy/colposcopy were excluded. Out of the 554 enrolled, 495 subjects were eligible for the study. The population of study subjects and their disease outcomes are listed in the following table.

		Clinician-collected Cervical (CC) HR-HPV	Self-collected Vaginal (SV) HR-HPV	Disease Outcomes		
Age category (years)	**Subjects N (%)**	**Positive N (%)**	**Positive N (%)**	**≤CIN1 N (%)**	**≥CIN2 N (%)**	**≥CIN3 N (%)**
Total	495 (100.0%)	311 (100.0%)	348 (100.0%)	388 (100.0%)	95 (100.0%)	72 (100.0%)
24-29	76 (15.4%)	49 (15.8%)	55 (15.8%)	58 (14.9%)	17 (17.9%)	10 (13.9%)
30-39	182 (36.8%)	111 (35.7%)	125 (35.9%)	139 (35.8%)	41 (43.2%)	32 (44.4%)
40-49	105 (21.2%)	65 (20.9%)	77 (22.1%)	82 (21.1%)	18 (18.9%)	14 (19.4%)
50-59	75 (15.2%)	51 (16.4%)	57 (16.4%)	61 (15.7%)	11 (11.6%)	10 (13.9%)
60+	57 (11.5%)	35 (11.3%)	34 (9.8%)	48 (12.4%)	8 (8.4%)	6 (8.3%)
Colposcopy Clinic Locations	**Subjects N (%)**	**Positive N (%)**	**Positive N (%)**	**≤CIN1 N (%)**	**≥CIN2 N (%)**	**≥CIN3 N (%)**
Total	495 (100.0%)	311 (100.0%)	348 (100.0%)	388 (100.0%)	95 (100.0%)	72 (100.0%)
Atlanta, GA	73 (14.7%)	33 (10.6%)	35 (10.1%)	59 (15.2%)	13 (13.7%)	9 (12.5%)
Chapel Hill, NC	67 (13.5%)	46 (14.8%)	48 (13.8%)	50 (12.9%)	16 (16.8%)	15 (20.8%)
Pittsburgh, PA	59 (11.9%)	32 (10.3%)	40 (11.5%)	47 (12.1%)	9 (9.5%)	2 (2.8%)
Cincinnati, OH	52 (10.5%)	35 (11.3%)	46 (13.2%)	46 (11.9%)	4 (4.2%)	4 (5.6%)
Birmingham, AL	38 (7.7%)	30 (9.6%)	27 (7.8%)	31 (8.0%)	7 (7.4%)	5 (6.9%)
Bronx, NY	50 (10.1%)	25 (8.0%)	34 (9.8%)	44 (11.3%)	6 (6.3%)	4 (5.6%)
Oklahoma City, OK	50 (10.1%)	39 (12.5%)	40 (11.5%)	36 (9.3%)	14 (14.7%)	13 (18.1%)
New Orleans, LA	26 (5.3%)	16 (5.1%)	20 (5.7%)	19 (4.9%)	6 (6.3%)	6 (8.3%)
Baltimore, MD	27 (5.5%)	17 (5.5%)	19 (5.5%)	23 (5.9%)	4 (4.2%)	3 (4.2%)
Richmond, VA	27 (5.5%)	17 (5.5%)	19 (5.5%)	20 (5.2%)	7 (7.4%)	4 (5.6%)
Houston, TX	18 (3.6%)	14 (4.5%)	14 (4.0%)	8 (2.1%)	7 (7.4%)	5 (6.9%)
San Juan, PR	6 (1.2%)	5 (1.6%)	4 (1.1%)	3 (0.8%)	2 (2.1%)	2 (2.8%)
Miami, FL	2 (0.4%)	2 (0.6%)	2 (0.6%)	2 (0.5%)	0 (0.0%)	0 (0.0%)

Once informed consent was obtained, each subject provided self-collected vaginal (SV) swab specimen followed by a clinician-collected cervical specimen (CC). For the SV specimen, participants were provided packaged self-collection kits with an instruction sheet on how to collect the vaginal specimens. No instruction was provided by the study staff. After collecting the vaginal swab, the subject broke the swab off into the empty BD Onclarity HPV Self Collection Tube. The clinician collected the cervical specimen using a cervical cytobrush/spatula or broom device and transferred the collected specimen into 20 mL of PreservCyt liquid-based-cytology (LBC) medium (Hologic, Inc., Bedford, MA, USA). The vaginal specimens were transported dry at ambient temperature to the laboratory where they were resuspended in 3mL of BD Onclarity HPV Assay diluent and tested on the BD COR System. The CC specimens in PreservCyt solution were shipped to one testing laboratory for testing with BD Onclarity HPV Assay. The linkage between CC and SV specimens were blinded. Cervical disease status was

based on standard of care (SOC) colposcopy and/or histopathology outcomes as reported by study sites.

The clinical sensitivity, clinical specificity and false positive rate in detecting precancer/cancer as well as the corresponding ratio between vaginal and cervical specimens were calculated. In addition, the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) of the BD Onclarity HPV Assay results between the two specimen types were calculated. The above study endpoints were calculated along with two-sided 95% confidence intervals (95% CI).
Of the 495 eligible subjects, 33 were excluded due to the following reasons:

1) 21 subjects were not tested for HPV due to various reasons (CC not collected, specimen collection errors and specimen contamination issues).
2) 12 subjects (eight with SV and four with CC specimens) had invalid HPV test results.

Therefore, the PPA and NPA between CC and SV specimen was evaluated based on results from 462 subjects. For an additional 12 subjects, colposcopy was not possible due to clinical reasons or patient factors. Therefore, these 12 subjects were excluded from the analyses of clinical sensitivity, clinical specificity, and clinical false positive rate as well as the corresponding ratio between vaginal and cervical specimens.

The study results are presented in the following tables.

≥CIN3			CC					
			HPV16 and/or HPV18	12 Other HR HPV	HR HPV Negative		Invalid	Total
					HPV DNA Detected	HPV DNA Undetected		
SV	HPV16 and/or HPV18		19	0	0	0	0	19
	12 Other HR HPV		0	37	2	0	0	39
	HR HPV Negative	HPV DNA Detected	0	5	0	0	0	7
		HPV DNA Undetected	1	1	0	0	0	
	Invalid		0	3	0	0	0	3
	Total		20	46	2		0	68
Sensitivity (SV): HR HPV = 89.2% (58/65) (95% CI: 79.4%-94.7%) Sensitivity (CC): HR HPV = 96.9% (63/65) (95% CI: 89.5%-99.2%) Ratio of Sensitivity (SV:CC): HR HPV = 0.921 (89.2%/96.9%); (95% CI: 0.814-1.018)								

≥CIN2			CC					
			HPV16 and/or HPV18	12 Other HR HPV	HR HPV Negative		Invalid	Total
					HPV DNA Detected	HPV DNA Undetected		
SV	HPV16 and/or HPV18		20	0	0	0	0	20
	12 Other HR HPV		1	49	2	0	0	52
	HR HPV Negative	HPV DNA Detected	0	6	1	2	0	14
		HPV DNA Undetected	1	1	0	3	0	
	Invalid		0	3	0	0	0	3
	Total		22	59	8		0	89

Sensitivity (SV): HR HPV = 83.7% (72/86) (95%CI: 74.5%-90.0%)
Sensitivity (CC): HR HPV = 90.7% (78/86) (95%CI: 82.7%-95.2%)
Ratio of Sensitivity (SV:CC): HR HPV = 0.923 (83.7%/90.7%); (95%CI: 0.832-1.003)

≤CIN1		CC				
		HPV16 and/or HPV18	12 Other HR HPV	HR HPV Negative	Invalid	Total
SV	HPV16 and/or HPV18	33	6	12	0	51
	12 Other HR HPV	2	162	33	3	200
	HR HPV Negative	3	12	101	1	117
	Invalid	0	3	2	0	5
	Total	38	183	148	4	373

Specificity (SV): HR HPV = 31.9% (116/364) (95%CI: 27.3%-36.8%)
Specificity (CC): HR HPV = 40.1% (146/364) (95%CI: 35.2%-45.2%)
Ratio of Specificity (SV:CC): HR HPV = 0.795 (31.9%/40.1%); (95%CI: 0.702-0.890)

False Positive Rate (FPR) (SV): HR HPV = 68.1% (248/364) (95%CI: 63.2%-72.7%)
False Positive Rate (FPR) (CC): HR HPV = 59.9% (218/364) (95%CI: 54.8%-64.8%)
Ratio of False Positive Rate (FPR) (SV:CC): HR HPV = 1.138 (68.1%/59.9%); (95%CI: 1.068-1.220)

Total		CC			
		HPV16 and/or HPV18	Other 12 HR-HPV	HR-HPV Negative	Total
SV	HPV16 and/or HPV18	57	6	13	76
	Other 12 HR-HPV	3	214	38	255
	HR-HPV Negative	4	19	108	131
	Total	64	239	159	462

PPA (HR HPV) = 92.4% (280/303); (95%CI: 88.9%- 94.9%)
NPA (HR HPV) = 67.9% (108/159); (95%CI: 60.3%-74.7%)

The final HPV assay invalid rate for SV is 1.63% (8/490; 95% CI: 0.83, 3.19%). The final HPV assay invalid rate for CC is 0.83% (4/480; 95% CI: 0.32, 2.12%)

A total of 17 Adverse Device Effects (ADEs) were reported in the study. All were mild and all resolved. No serious adverse events (SAEs) or unanticipated ADEs (UADEs) were reported.

Study #2

A second prospective clinical study was conducted to provide data supporting the performance of Onclarity Self-Collection Kit for use with the BD Onclarity HPV Assay. This study was conducted in a simulated home environment with individuals representative of the general cervical cancer screening population in the U.S. 406 subjects were enrolled at two locations in the eastern and western regions of the U.S. Subjects, aged between 25-65 years old, who met

routine cervical cancer screening guidelines and had no previous history of abnormal cervical cancer screening results were consented for the study. 5 subjects were excluded due to pelvic pain and not meeting the required age range. Each participant was provided an individually packaged self-collection kit and an instruction sheet on how to collect the vaginal specimen. No instruction was provided by the study staff. After collecting the vaginal swab, subjects broke the swab off into the empty BD Onclarity HPV Self Collection Tube. A clinician then collected a cervical specimen using a cervical broom and expressed it in 20 mL of PreservCyt liquid-based-cytology (LBC) medium (Hologic, Inc., Bedford, MA, USA). The vaginal specimens were transported dry at ambient temperature to the laboratory where they were resuspended in 3 mL of BD Onclarity HPV Assay diluent and tested on the BD COR System. The clinician-collected specimens were shipped to a laboratory and tested with BD Onclarity HPV Assay on BD COR System.

The Positive Percent Agreement was 93.1% (95% CI: 85.8%, 96.8%). The Negative Percent Agreement was 83.1% (95% CI: 78.6%, 86.9%). The age distribution of the participants and study results are presented in tables below.

The final HPV assay invalid rate for SV and CC is 0%. No adverse events were reported in the study.

Age Distribution of Study Participants

Age category (years)	Subjects N (%)
Total	401
24-29	19 (4.74%)
30-39	62 (15.46%)
40-49	98 (24.44%)
50-59	141 (35.16%)
60+	81 (20.20%)

Concordance: Cross-Tabulation of CC vs. SV Results and Key Performance Metrics

Total		**CC**		
		HR HPV Positive	**HR HPV Negative**	**Total**
SV	**HR HPV Positive**	81	53	134
	HR HPV Negative	6	261	267
	Total	87	314	401
PPA (HR HPV) =93.1% (81/87); 95% CI: 85.8%, 96.8% NPA (HR HPV) =83.1% (261/314); 95% CI: 78.6%, 86.9				

Please refer to P160037-S017 and P160037-S024 for additional information on self-collected vaginal specimen testing.

The results from the studies submitted in this premarket notification demonstrate that the Onclarity Self-Collection kit is substantially equivalent to the predicate device.