

K260184 Onclarity™ Self-Collection KitApr 2, 2026
71 days to decisionK260184 · Product code: **SEP** · Microbiology
Source: <https://www.510kdatabase.net/k260184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device For Home Collection And Transport Of Vaginal Specimens By Lay Users For Use In An Approved Hpv Molecular Assay (SEP)
Date received	Jan 21, 2026
Decision date	Apr 2, 2026
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Becton, Dickinson and Company
Location	Franklin Lakes, NJ, US
Contact	Joseph Basore
Website	https://www.bd.com
510(k) history	134 submissions · 134 cleared · 2010-2026

Becton, Dickinson and Company is an American multinational medical technology company headquartered in Franklin Lakes, New Jersey. BD manufactures and sells medical devices, instrument systems, and reagents globally. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions spanning 2010 to 2026. BD's cleared devices span multiple categories including microbiology systems, blood collection products, and general hospital devices. The company's latest clearance in 2026 reflects continued innovation and regulatory engagement...

CLINICAL EVIDENCE - NCT06498661**Self-collection for HPV Testing to Improve Cervical Cancer Prevention (SHIP) Trial (LMI-001-A-S01)**

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	750 patients (estimated)
Study sites	15 sites
Condition studied	Cervical Carcinoma; Human Papillomavirus Infection
Primary purpose	Prevention
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jun 30, 2027
Sponsor	National Cancer Institute (NCI) (Nih)

Primary outcome

Clinical sensitivity for self-collected (SC) samples (Group A)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06498661