FDA 510(k) Premarket Notification

K200748 Visby Medical Sexual Health

CLEARED

Aug 26, 2021
521 days to decision

K200748 · Product code: **QEP** · Microbiology
Source: https://www.510kdatabase.net/k200748/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Mar 23, 2020
Decision date	Aug 26, 2021
Days to decision	521 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Visby Medical**
Location	San Jose, CA, US
Contact	Carolyn Glickman
510(k) history	2 submissions · 2 cleared · 2021-2023

CLINICAL EVIDENCE - NCT04098900

Clinical Evaluation of the Click Sexual Health Test for the Detection of Neisseria Gonorrhoeae (NG), Trichomonas Vaginalis (TV), and Chlamydia Trachomatis (CT) in Women

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	309 patients (actual)
Study sites	5 sites
Condition studied	Chlamydial Infection; Gonococcal Infection; Trichomoniasis
Study type	Observational
Completion date	Dec 3, 2019
Sponsor	Visby Medical (Industry)

Primary outcome

The percent sensitivity and specificity of the Click Device for detection of CT in self-collected vaginal specimens as compared to Patient Infected Status (PIS) using vaginal specimens collected by a qualified Health Care Provider (HCP)

Secondary outcome

Usability will be measured by 5-point Likert scale responses, yes/no questions, and open text questions from study operators.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04098900