DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K190463

Device Name

Cepheid Xpert® C. difficile/Epi Control Panel

Indications for Use *(Describe)*

The Cepheid Xpert® C. difficile/Epi Control Panel is intended for use as external assayed positive and negative quality controls to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Clostridioides (Clostridium) difficile* performed with the Cepheid Xpert® C. difficile/Epi assay on the GeneXpert® Dx System. The controls comprise cultured and inactivated *Clostridioides (Clostridium) difficile* 027-NAP1-B1 as the positive control and *Clostridium sordellii* as the negative control.

The Cepheid Xpert® C. difficile/Epi Control Panel is not intended to replace manufacturer controls provided with the device.

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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