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)*

K183366

Device Name

GenePOC Strep A

Indications for Use *(Describe)*

The GenePOC Strep A assay, performed on the revogene instrument, is an automated, qualitative *in vitro* diagnostic test that utilizes real-time polymerase chain reaction (PCR) for the direct detection of *Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*) nucleic acids from throat swab specimens obtained from patients with signs and symptoms of pharyngitis. The GenePOC Strep A assay is intended for use as an aid in the diagnosis of Group A *Streptococcus* infection.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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