DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182038

Device Name

URiSCAN 10ACR urine strips on the URiSCAN Optima urine analyzer

Indications for Use *(Describe)*

The URiSCAN 10 ACR urine strips on the URiSCAN Optima urine analyzer are intended for the in vitro qualitative and semi-quantitative measurement of the following parameters: blood, ketones (acetoacetic acid), protein, nitrite, glucose, pH, SG (specific gravity), leucocytes, albumin and creatinine and the determination of the ACR (albumin creatinine ratio). These measurements are useful in the evaluation of renal, urinary and metabolic disorders.

The URiSCAN Optima urine analyzer is intended to read the color change on the test pads found on the URiSCAN 10ACR urine strips and to display and print the results.

The URiSCAN 10ACR urine strips include test pads for the following parameters: blood, ketones (acetoacetic acid), protein, nitrite, glucose, pH, SG (specific gravity), leucocytes, albumin and creatinine, and can only be read on the URiSCAN Optima urine analyzer.

The URiSCAN 10ACR urine strips on the URiSCAN Optima urine analyzer are intended for prescription use only, in clinical laboratory and in point-of-care settings.

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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