

K182038 URiSCAN 10ACR urine strips on the URiSCAN Optima urine analyzerDec 10, 2018
133 days to decisionK182038 · Product code: JFY · Chemistry
Source: <https://www.510kdatabase.net/k182038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Jul 30, 2018
Decision date	Dec 10, 2018
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Yd Diagnostics Corporation
Location	Yongin-Si, KR
Contact	Hyuckjoo Lee
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Ammirati Regulatory Consulting
Contact	Erika B. Ammirati

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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