

K183648 APAS Independence with Urine Analysis ModuleMay 15, 2019
140 days to decisionK183648 · Product code: **PPU** · Microbiology
Source: <https://www.510kdatabase.net/k183648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microbial Colony Image Assessment System (PPU)
Date received	Dec 26, 2018
Decision date	May 15, 2019
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Clever Culture Systems AG
Location	Baech, CH
Contact	Julie Winson
510(k) history	2 submissions · 1 cleared · 2016-2019

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