

K190341 iC-GN iC-Cassette for use on the iC-SystemJun 28, 2019
134 days to decisionK190341 · Product code: **PEN** · Microbiology
Source: <https://www.510kdatabase.net/k190341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gram-negative Bacteria And Associated Resistance Markers (PEN)
Date received	Feb 14, 2019
Decision date	Jun 28, 2019
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Icubate, Inc.
Location	Huntsville, AL, US
Contact	Carter Wells
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	MDC Associates, LLC
Contact	Fran White

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

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