

K163390 iC-GPC Assay TM for use on the iC-SystemTMAug 8, 2017
249 days to decisionK163390 · Product code: **PAM** · Microbiology
Source: <https://www.510kdatabase.net/k163390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gram-positive Bacteria And Their Resistance Markers (PAM)
Date received	Dec 2, 2016
Decision date	Aug 8, 2017
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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