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510(k) Summary Statement

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Device Name:	Gram Negative Identification Plus (GNI+) Card
Classification	Automated Microorganism Differentiation and Identification Device Class I
Substantial Equivalence Claim:	bioMérieux Vitek, Inc. Gram Negative Identification (GNI) Card

Device Description:

The GNI+ Card consists of a plastic card with thirty wells that contain 28 dehydrated biochemical broths, one negative control broth and one growth control broth. The broths are re-hydrated with a saline suspension of a pure culture isolated from a patient specimen. The GNI+ Card performs a variety of conventional and non-conventional biochemical tests that are based on established biochemical methods. Organism identification usually requires between 2-12 hours of incubation on the automated Vitek System.

Intended Use:

The Vitek GNI+ Card is intended to be used in conjunction with the Vitek System for the automated identification of microorganism of the family *Enterobacteriaceae*. In addition, a select group of glucose non-fermenting gram-negative bacteria, and members of the family *Vibrionaceae* can be identified. In addition to the organisms currently claimed with the GNI Card, the GNI+ Card has added the following 13 new organism claims:

Aeromanas veronii biovar veronii
Budvicia aquatica
Burkholdenia mallei
CDC Group EO-2
Chromobacterium violaceum
Edwardsiella hoshinae
Klebsiella ornithinolytica
Moellerella wisconsensis
Rahnella aquatilis
Shigella boydii/flexneri
Sphingobacterium spiritivorum
Sphingobacterium thalpophilum
Yokenella regensburgei (Koserella trabulsii)

Technological Characterisitics

The GNI + Card maintains the same technological characteristics as GNI, i.e., conventional and nonconventional biochemical tests that are selectively metabolized by bacteria, resulting in reactivity biopatterns that may be photometrically read and analyzed by the automated Vitek System .

Non Clinical Development Trials

A panel of 2974 strains were used to develop the GNI + database. These organism were well characterized, having been previously previously identified by the GNI Card, API strips and/or conventional biochemicals. The GNI + Card correctly identified 96.9% of the tests run.

Clinical Trials

Three clinical sites conducted the trials.

Trial Design

The performance claims of the GNI+ card were validated by directly comparing to the current Vitek GNI Card. Discrepancies between the GNI+ and the current GNI were resolved by the API 20E (fermenters) or the API NFT (non-fermenters). Further discrepancies and also any sample that was identified by the GNI+ card as a species not claimed by the reference methodology(ies) was confirmed with conventional biochemical testing.

A panel of 106 challenge organisms bioMérieux Vitek which cover the range of the GNI+ card's performance claims, were tested. The challenge organisms were different isolates than those used to develop the database. Extremely rare or pathogenic organisms were excluded from this challenge set. A minimum of 130 routine clinical isolates were tested. These isolates were from fresh patient cultures as they were randomly submitted to the laboratory. Thirty to fifty isolates from the investigator's stock collection were tested in addition to the 130 clinical isolates. The GNI+ Card identified the challenge set provided by bioMérieux Vitek correctly 94.7% of the time. Overall correlation of GNI+ compared to GNI was 97.4%

Software Testing

GNI+ software analysis rules were tested extensively in-house and were also run at the clinical trial sites. A detailed protocol was established to challenge the performance of the GNI+ card based on the software specification. This software was designed, validated and tested according to established written procedures.

Safety and Effectiveness Issues

The GNI+ data validates that the performance characteristics are reproducable, safe and effective. No adverse discrepancies were noted in the comparison studies. When used according to the package insert directions, the GNI+ Card will perform as claimed.

Conclusions

The modifications to the database in order to incorporate the 13 new strains does not affect the safety or effectiveness of the GNI+ card, as demonstrated by the data included in this premarket notification. Overall correlation of GNI+ compared to GNI was 97.4%