Nexogen, Inc.

Clinically Significant Concern Addressed and Intended Use of the Proposed Device

The emergence of antibiotic resistance in bacteria presents an enormous challenge since the treatment of many bacterial infections using available antibiotics is becoming increasingly limited, and in some cases, nonexistent. Based on CDC reports, 2 million people acquire antibiotic-resistant infections each year and about 23,000 patients die**1**. Recently, an alarming increase of various types of antimicrobial-resistant gram-negative bacteria is observed2, even in children hospitalizations3, including extended-spectrum b-lactamase (ESBL)–producing *Enterobacteriaceae*, carbapenem-resistant *Enterobacteriaceae (*CRE), and multidrug-resistant strains of *Pseudomonas aeruginosa* and *Acinetobacter baumannii*.4 Healthcare-associated infections (HAI) complicate over 10% of all hospitalizations and up to 75% of those hospitalizations are caused by pathogenic bacteria that are resistant today to the first-line of antimicrobial therapy. This significantly increases morbidity and mortality in HAI and increased annual healthcare costs in US to over $20 billion. Timely and rapid diagnostics of bacterial infections and recognition of their resistance toward specific antibiotics is becoming a critical step in implementing measures to reduce unnecessary or ineffective prescriptions of antibiotics. A practice of frequently prescribing antibiotics, when they may not be needed, promotes evolutionary or selective pressures toward the development of new strains of antibiotic resistance bacteria. DNA-based, molecular diagnostics technologies provide a finger-print type identification of both bacterial species and their resistance genes. This project proposes development of a ***new POC DNA microarray platform*** and an ***assay correlating the resistance genes with antibiotics susceptibility*** for ***outpatient applications, that will target clinics, emergency rooms, urgent care centers*** and ***physician offices.***