



NanoSafe™ Coatings Establishing A Device Master File for Anti-microbials

NanoSafe has patented an anti-microbial coating that can be permanently applied to metal, plastic and fabrics to provide bacterial and viral resistance

JUPITER, FL, USA, November 16, 2015 /EINPresswire.com/ -- NanoSafe Coatings today announced the initiative to establish a Master Device File (MDF) with the FDA to insure that Medical Device companies seeking [anti-microbial coating](#) protection for medical products can expedite the 510(k) process. NanoSafe is an innovative leader with a patented technology that provides a non-leaching, permanent, non-super bug promoting coating that can be applied to metals, plastics and fabric that comprise [medical devices](#).

The MDF will provide the FDA with validation aspects of the NanoSafe technology in the areas of:

- Formulation
- Manufacturing
- Antimicrobial Mechanism of Action
- Demonstration of Permanent binding
- Assessments of toxicity and leachables
- Biocompatibility
- Stability.

NanoSafe has developed a unique pilot program for companies to test the NanoSafe coating on medical devices called the NanoSafe CRADA, where-in a medical device or component can be sent for anti-microbial coating to the NanoSafe Contract Manufacturing facility and subsequently be tested for both bacterial and viral "killing" efficacy.

The CRADA also provides a Company with a Regulatory Assessment as to the viability and pathway required to combine the NanoSafe anti-microbial coating to a medical device and the testing pathways required under 510(k) guidelines. This Assessment will provide the key parameters of potential anti-microbial product claims, device classifications, and testing required for a successful 510(k) filing and approval by the FDA.

It is well known that "Healthcare-associated infections (HAIs), many of which are caused by antibiotic-resistant bacteria, impact one in 25 patients in the United States each year. These preventable infections claim the lives of 75,000 people and cost the healthcare industry between \$36 billion and \$45 billion annually."

NanoSafe provides a viable alternative to heavy-metal applications for anti-microbial protection on medical devices to combat the causes of HAIs and welcomes Companies to initiate Pilot Studies with NanoSafe™.

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