Title: **Rethinking Medical Device Testing: The Rise of NAMs**

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Abstract:

Rethinking Medical Devices Testing: The Rise of NAMs

The testing of medical devices is undergoing a profound transformation as new approach methodologies (NAMs) gain recognition for their scientific, ethical, and regulatory value. Moving beyond traditional animal-based models, NAMs—including in vitro, in silico, and organ-on-a-chip technologies—are proving to be more human-relevant, reproducible, and cost-efficient than conventional animal testing. This shift is driven not only by scientific innovation but also by growing global momentum. Institutions such as the U.S. NIH of FDA have recently reinforced their commitment to advancing alternatives to animal testing, signaling a broader systemic change. In the field of medical devices, NAMs are increasingly used in the assessment of cytotoxicity, irritation, and sensitization, aligning with regulatory requirements and the principles of modern human safety evaluation. As confidence in these models grows, so does their potential to replace or complement traditional approaches. Rethinking testing strategies and regulatory frameworks is no longer optional—it is an essential evolution toward more ethical, efficient processes and safer products for end users.