

## **A Resolution to Amend the Food and Drug Administration Medical Device Amendments**

1   **WHEREAS,**   medical devices have evolved in complexity and population since the  
2                   implementation of the Medical Device Amendments in 1976; and

3   **WHEREAS,**   the system of testing medical devices and products is faulty and  
4                   dangerous to public health; and

5   **WHEREAS**   companies and sponsors of medical devices produce unsafe products  
6                   which can cause lifelong medical issues and/or death of U.S. Citizens;  
7                   now, therefore, be it

8   **RESOLVED,**   By the Congress here assembled that by January 1<sup>st</sup>, 2025, the Food and  
9                   Drug Administration shall:

10                   **(A)** Amend the Medical Device Amendments to eliminate the Pre-Market  
11                   Approval Process.

12                   **(B)** Require at least three clinical trials with long term studies of the  
13                   device with at least one-hundred patients altogether.

14                   **(C)** Create a new application titled the “Investigational New Medical  
15                   Device Application”.

16                   **(D)** Implement a Review team for approved applications to study the  
17                   evaluate research and the device’s safety and effectiveness.

18                   **(E)** Prohibit devices to bypass the approval process.