

119TH CONGRESS
1ST SESSION

H. R. 88

To amend the Federal Food, Drug, and Cosmetic Act to exempt from regulation as devices non-invasive diagnostic devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 3, 2025

Mr. BIGGS of Arizona introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to exempt from regulation as devices non-invasive diagnostic devices, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Innovation Ac-
5 celeration Act of 2025”.

6 **SEC. 2. EXEMPTING NON-INVASIVE DIAGNOSTIC DEVICES**
7 **FROM REGULATION AS DEVICES.**

8 Section 201(h) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 321(h)) is amended—

1 (1) by striking “section 520(o)” and inserting
2 the following: “section 520(o) or any non-invasive di-
3 agnostic device”; and

4 (2) by adding at the end the following: “For
5 purposes of the preceding sentence, the term ‘non-
6 invasive’ means, with respect to a diagnostic device,
7 that the device does not penetrate the skin or any
8 other membrane of the body, is not inserted or im-
9 planted into the body, causes no more than ephem-
10 eral compression or temperature changes to in situ
11 bodily tissues, and does not subject bodily tissues to
12 ionizing radiation.”.

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