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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R.

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

Mr. BIGGS introduced the following bill; which was referred to the Committee on _____

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 2022”.

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

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

5 (1) in the second sentence by inserting before
6 the period at the end the following: “or any non-
7 invasive diagnostic device”; and

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