

117TH CONGRESS  
2D SESSION

# H. R. 6513

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

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 28, 2022

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

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## 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”.

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) in the second sentence by inserting before  
2           the period at the end the following: “or any non-  
3           invasive diagnostic 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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